Clinical Study Report

Title Page

Study Title: "A Retrospective study to assess the effectiveness of Petshuddhi Churna in the treatment of Constipation"

Protocol No.	MGCTSR6
Version Number and Date	Version 1.0 dated 02 June 2025
Investigational Product	Petshuddhi Churna
Name & Address of Sponsor	Jeena Sikho Lifecare Limited, Panchkula, India
Name & Affiliation of the Investigator(s)	Dr. Monu Pathak Hospital & Institute of Integrated Medical Sciences, Meerut
No. of patients/records	100
Report Number	MGCTS/CT/R6
Date of the draft report	13 June 2025

Confidential

The information in this document is confidential and is to be used only in connection with matters authorized by Jeena Sikho Lifecare Limited and Mittal Global Clinical Trial Services and no part of it is to be disclosed to the others without prior written permission from the either organization. This study was performed in accordance with NDCT Rules 2019, ICHGCP E6 (R2), Schedule-Y (2017) and Ethical Principles as per the Declaration of Helsinki (2013) including archiving of all the essential documents

INVESTIGATOR(S) SIGNATURE(S)

Study Title:

A Retrospective study to assess the effectiveness of Petshuddhi Churna in the treatment of Constipation

I have read this report and confirm that to the best of my knowledge it accurately describes the conduct and results of the study.

Dr. Monu Pathak Principal Investigator Hospital & Institute of Integrated Medical Sciences, Meerut	*Monu Pathak* **13 June 2025** **SIGNATURE & DATE**

STATEMENT OF COMPLAINCE

A Clinical study titled: "A Retrospective study to assess the effectiveness of Petshuddhi Churna in the treatment of Constipation".

This study was conducted in compliance with the final protocol, the applicable Harmonized Tripartite Guidelines for Good Clinical Practice (GCP), the relevant sections of Good Laboratory Practice (GLP), local laws and regulations and the provisions of Declaration of Helsinki.

Name	**Designation & Address**	**Signature**	**Date** **(DD MMM YYYY)**
PUNEET MITTAL	Director- Clinical Research, MGCTS, Mittal Building 121-B, Mansarovar Ind Estate, Panchli, Baghpat Road, Meerut-250002, India		13 June 2025

STATEMENT OF COMPLAINCE
(DATA SAFETY MONITORING BOARD)

A Clinical study titled: "A Retrospective study to assess the effectiveness of Petshuddhi Churna in the treatment of Constipation"

This study was verified and reviewed independently according with the final protocol, the applicable Harmonized Tripartite Guidelines for Good Clinical Practice (GCP), the relevant sections of Good Laboratory Practice (GLP), local laws and regulations and the provisions of Declaration of Helsinki.

S. No	Name and Designation	Signature	Date (DD MMM YYYY)
2	**Ms. Nidhi Dixit** **Study Director,** **MGCTS- Meerut**		12 June 2025
3	**Sheetal** **Data Management Associate** **MGCTS- Meerut**		12 June 2025

1. REPORT SUMMARY:

Title of the Study	A Retrospective study to assess the effectiveness of Petshuddhi Churna in the treatment of Constipation
Investigational Product	Petshuddhi Churna
Name of Sponsor	Jeena Sikho Lifecare Limited
Investigator (s)	**Dr. Monu Pathak** Principal Investigator Hospital & Institute of Integrated Medical Sciences, Meerut
Study Objective	**Primary objective:** • The primary objective was to evaluate the efficacy of Petshuddhi Churna for patients with Constipation.
Study Phase	NA
Study Design	This trial was a retrospective study to assess the efficacy of Petshuddhi Churna when administered for up to 30 days to adults with Constipation. The Investigator's consent was taken prior to accessing the patient case files who was on the treatment of Petshuddhi Churna for 30 days in the past 3 months. The case records with the data for Abdominal Discomfort, Stool Consistency and Complete Bowel movement were only considered. Patient case records must have data from day 1(Visit 1), and day 30 (visit 2) to be considered for analysis in this study.
Number of subjects	100

Study Inclusion Criteria	Subject records were included based on the following criteria. 1. Subjects of either sex 2. Age 18 - 65 years (both inclusive) 3. Chronic Constipation Subjects 4. Subject record has Abdominal Discomfort data for baseline and day 30 5. Subject record has Stool consistency and total defecation for baseline and day 30
Study Exclusion Criteria	Subject records were excluded based on the following criteria. 1. Were pregnant or breast-feeding. 2. Patients requiring the use of antibiotics either in medicine form of natural (e.g. grapefruit seed extract, olive leaf extract, oil of oregano, colloidal silver and highly concentrated garlic preparations) 3. Patients requiring treatments with non-permitted medication (i.e. 5- HT3 antagonist, spasmolytics, anticholinergics, cholestyramine, anti- flatulence agents, metoclopramide, gastric-anti secretory agents (proton pump inhibitors; for indications other than Gastroesophageal Reflux Disease (GERD)), narcotics, anti-diarrheal drugs, and systemic steroids) 4. Patient had a potential central nervous system cause of constipation (e.g., Parkinson's disease, spinal cord injury, and multiple sclerosis). 5. Patient had untreated hypothyroidism or treated hypothyroidism for which the dose of thyroid hormone had not been stable for at least 6 weeks at the time of the Screening. 6. Have used immunosuppressive or immunomodulatory medication (i.e., biologics), including oral orparenteral corticosteroids.
Test Product, Dose	**Test Product:** Petshuddhi Churna, 1 tsp daily during bedtime **Route of Administration:** Oral

Study Methodology	The Investigator's consent was taken prior to accessing the patient case files who was on the treatment of Petshuddhi Churna for 30 days in the past 3 months. The case records with the data for Abdominal Discomfort, Stool Consistency and Complete Bowel movement were only considered. Patient case records must have data from day 1(Visit 1), and day 30 (visit 2) to be considered for analysis in this study. The study had the following visits **Visit 1 (Day 1):** Beginning of Study(Dispensing to the Subject) **Visit 2 (Day 30):** End of Study
Primary Outcome	• Effectiveness of Petshuddhi Churna in decreasing constipation Symptoms as Differences in abdominal discomfort, stool consistency and complete defecation.
Secondary Outcome	NA
Statistical Analysis	Prior to the analysis of the final studied data, a detailed statistical analysis planned (sap) had been written describing all analyses that had been performed. Data had been analyzed used NCSS software appropriate statistical test.
Ethical Conduct of the study	The study was initiated after written approval from the hospital's Institutional Ethics Committee. The trial was conducted as per NDCT Rule 2019, ICH GCP E6 R2 Guidelines, Schedule Y (2017), Declaration of Helsinki (Brazil, 2013) and in accordance with other applicable guidelines.
Efficacy Results	Age of the cases in this study ranged from 20 to 65 years with average age 38.16 years among treatment group. 50% of the cases among the treatment group were male and 50% female. Average BMI of the patients among treatment group was 22.93 Kg/m2. Complete Spontaneous Bowel Movement: 8% of the cases among the treatment group at baseline had complete spontaneous bowel movement. After 30 days of treatment 84% of the cases among treatment group complete spontaneous bowel movement. This

	indicates that Petshuddhi Churna helps in complete defecation. Average abdominal discomfort score at baseline among the treatment group was 4.92 which was indicative of Medium abdominal discomfort. After 30 days of treatment the abdominal discomfort score among the treatment group was 1.42 showing clinically significant improvement in the abdominal discomfort when compared to the baseline. This indicates that the abdominal discomfort reduces to a good level when used for 30 days regularly. Average stool consistency score at baseline among the treatment group was 1.78 which was indicative of stool consistency like a sausage with cracks. After 30 days of treatment the mean stool consistency score among the treatment group was 2.90 which was indicative of stool consistency like a sausage but crumby and smooth on the surface which was significant from the baseline. This indicates that that stool consistency gets better when you use Petshuddhi Churna for 30 days. The test and reference product were well tolerated by the patients. No adverse event was reported during the study. All the vital signs were found normal at baseline and the end visit. Concomitant medications were allowed only for Fever or any physical injury during the study treatment period on SOS basis apart from the ones subjects take as their routine prior medication. There were no protocol violations and deviations reported. No death, serious or severe adverse events were reported during the conduct of the study.
Conclusion	Petshuddhi Churna was effective in maintaining and treating the constipation symptoms. In conclusion, there was significant change from the baseline till the end of the treatment among most of the efficacy parameters observed. Petshuddhi Churna was effective in maintaining and treating the constipation symptoms, such as Complete spontaneous Bowel Movement, Abdominal Discomfort and Stool Consistency. No adverse events were reported by the patients after using Petshuddhi Churna indicating that it was well tolerated and thus safe to use.
Date of Report	13 June 2025

Table of Contents

2. List of Abbreviations

Abbreviation	Definition
AE	Adverse event
ANOVA	Analysis of variance
AUC	Area under the curve
COA	Certificate of Analysis
CI	Confidence interval
CRO	Contract Research Organization
DCGI	Drug Controller General of India
eCRF	Electronic case report form
ED	Early Discontinuation
END	Endoscopy
EoT	End of Treatment
EoS	End of Study
EMEA	European Medicines Evaluation Agency
gm	Gram
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
FDA	Food and Drug Administration
Hrs.	Hours
ICD	Informed Consent Document
ICH	International Council for Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use
ICMR	Indian Council of Medical Research
IEC	Institutional Ethics Committee
IMP	Investigational Medicinal Product
IP	Investigational product
IRB	Institutional Review Board
Kg	Kilograms
Ltd.	Limited

MedDRA	Medical Dictionary for Regulatory Activities
mg/dL	milligram/deciliter
mL	Milliliter
No.	Number
NICE	National Institute for Health and Care Excellence
OTC	Over the counter
QA	Quality Assurance
QOL	Quality of Life
PRO	Patient-reported outcome
SAE	Serious Adverse Event
SAP	Statistical analysis plan
SD	Standard Deviation
SOP	Standard Operating Procedure
SUSAR	Suspected unexpected serious adverse reaction
TC	Telephone call
U	Units
ULN	Upper limit of normal
UPT	Urine Pregnancy Test
USV	Unscheduled Visit
°C	Degree Celsius
°F	Degree Fahrenheit
%	Percent

3. ETHICS

3.1. Independent Ethics Committee (IEC) or Institutional Review Board(IRB)

The study documents [Protocol, CRF, final CTA, CV, MRC and Undertaking of Investigator] were reviewed by the Institutional Ethics Committee for each center, as listed in Appendix.

Site ID	Name of Investigator	Site	Ethics Committee
A	Dr. Monu Pathak	Hospital & Institute of Integrated Medical Sciences, Meerut	ARMHRC institutional Ethics Committee, Meerut- UP

3.2. Ethical Conduct of the Study

The study was conducted as per requirements of ICMR Guidelines for Biomedical Research on Human Subjects, International Conference on Harmonization (Step 5) 'Guidance on Good Clinical Practice', New Drugs and Clinical Trials Rules (2019) of India, Declaration of Helsinki (Fortaleza, Brazil, October 2013) and with procedures oriented to Good Laboratory Practice, EMEA guideline and applicable regulatory guidelines, guideline ethical requirements of directive 2001/20/EC and applicable regulatory guidelines.

3.3. Patient Information and Consent

All patients provided written informed consent to participate in the study prior to being screened. The patient information sheet detailed the procedures involved in the study (aims, methodology, potential risks and anticipated benefits) and the investigator explained these to each patient. The patient signed the consent form to indicate that the information had been explained and understood. The patients were allowed to take ample time to consider the information presented before signing and dating theinformed consent form to indicate that they fully understood the information, and willingly volunteered to participate in the study. The patients were given a copy of thesigned informed consent form for their information. The original informed consent documents were kept in a confidential file in the Investigators site record.

4. Investigators and Study Administrative Structure

Sponsor	Jeena Sikho Lifecare Limited, Panchkula
Principal Investigator (S)	Dr. Monu Pathak Hospital & Institute of Integrated Medical Sciences, Meerut
ETHICS COMMITTEE (S)	ARMHRC Institutional Ethics Committee
SITE(S) ADDRESS	Hospital & Institute of Integrated Medical Sciences, Meerut
REPORT GENERATION	Ms. Nidhi Dixit

5. INTRODUCTION

Constipation is a functional gastrointestinal (GI) disorder characterized by recurrent symptoms of abdominal discomfort, accompanied by slow bowel function and a feeling of bloating, moderate to severe cases of constipation, an overall deterioration in quality of life (QOL) is often present. Gut microbiota plays important role in the maintenance of gut homeostasis by direct bactericidal effect and the evolution of both innate and adaptive immune system. Gut microbiota plays important role in pathogenesis of constipation. This is evident from the fact that constipation occurs more frequently after intestinal infections and antibiotic treatment. Considering the relationship between gut microbiota and inflammation of gut, selective manipulation of gut microbiota by sennosides and other herbs appears to be an ideal treatment modality for constipation.

Petshuddhi Churna is a combination of proven herbs in Ayurveda which includes,

- Cassia angustifolia
- Emblica officinalis
- Terminalia bellerica
- Terminalia chebula
- Operculina turpenthum
- Aegle marmelos
- Cassia fistula
- Trachyspermum ammi
- Zingiber oficinale
- Foeniculum vulgare
- Rosa centifolia
- Syzygium aromaticum
- Black Salt (Kali muriaticum)

The assessment of efficacy was done as retrospective based on the existing case reports obtained from the existing patient base from the test site.

6. STUDY OBJECTIVES

6.1. Primary objective:

- The primary objective was to study the efficacy of Petshuddhi Churnafor patients with Constipation by assessing Symptoms as Differences in abdominal discomfort, stool consistency and complete defecation.

6.2. Secondary Objective:

The secondary objectives were:

- To study the satety of Petshuddhi Churna

7. INVESTIGATIONAL PLAN

7.1. Overall Study Design and Plan-Description

This trial was a retrospective clinical study to assess the efficacy of Petshuddhi Churna when administered for up to 30 days to adults with Constipation

The Investigator's consent was taken prior to accessing the patient case files who was on the treatment of Petshuddhi Churna for 30 days in the past 3 months. The case records with the data for Abdominal Discomfort, Stool Consistency and Complete Bowel movement were only considered. Patient case records must have data from day 1(Visit 1), and day 30 (visit 2) to be considered for analysis in this study.

The study had the following visits

Visit 1 (Day 1): Beginning of Study(Dispensing to the Subject)

Visit 2 (Day 30): End of Study

7.2. Mode of Administration:

Only the case records were considered where each study patient self-administered **Orally** one of test product once daily preferably at the same time every day for 30 days.

Primary endpoint and Secondary endpoint assessment was performed at Visit 2 (Day 30). Being retrospective study, no regular safety check was performed as part of the process.

8. Discussion of Study Design

The primary efficacy endpoint for the study was to measure the overall symptoms relief by assessing differences in abdominal discomfort, stool consistency and complete defecation.

8.1. Selection of Study Population

The patient's records were selected by an Investigator based on inclusion and exclusion criteria.

8.1.1. Inclusion criteria

Subject records were included based on the following criteria.:

1. Subjects of either sex
2. Age 18 - 65 years (both inclusive)
3. Chronic Constipation Subjects
4. Subject record has Abdominal Discomfort data for baseline and day 30
5. Subject record has Stool consistency and total defecation for baseline and day 30

It was investigator's responsibility to ensure that the subjects records are in compliance with the inclusion criteria.

8.1.2. Exclusion criteria

Subject records were excluded based on the following criteria:

1. Were pregnant or breast-feeding.
2. Patients requiring the use of antibiotics either in medicine form of natural (e.g. grapefruit seed extract, olive leaf extract, oil of oregano, colloidal silver and highly concentrated garlic preparations)
3. Patients requiring treatments with non-permitted medication (i.e. 5- HT3 antagonist, spasmolytics, anticholinergics, cholestyramine, anti- flatulence agents, metoclopramide, gastric-anti secretory agents (proton pump inhibitors; for indications other than Gastroesophageal Reflux Disease (GERD)), narcotics, anti-diarrheal drugs, and systemic steroids)
4. Patient had a potential central nervous system cause of constipation (e.g.,

Parkinson's disease, spinal cord injury, and multiple sclerosis).

5. Patient had untreated hypothyroidism or treated hypothyroidism for which the dose of thyroid hormone had not been stable for at least 6 weeks at the time of the Screening.
6. Have used immunosuppressive or immunomodulatory medication (i.e., biologics), including oral or parenteral corticosteroids.

8.2. Treatments

8.2.1. Treatments administered

Test product (T): Petshuddhi Churna

8.2.2. Mode of Administration:

Oral, once daily preferably at the same time(bedtime) every day for 30 days.

8.2.3. Identity of investigational product(s)

Table 1: Identity of Investigational Test Product

Test product	:	Petshuddhi Churna
Manufactured by	:	Jeena Sikho Lifecare Limited, Germany
Lot No.	:	PS01
Manufacturing Date	:	March 2025

8.2.4. Selection of doses in the study

The subject records where the patient took a dosage of one once daily for 30 days were considered.

8.3. Prior and concomitant therapy

8.3.1. Concomitant medications:

Any allowed concomitant medication being taken by the patient was continued on same dose during the study. Administration of any other constipation medications was not permitted after screening till the end of study.

8.3.2. Prohibited Medications

- Treatments like 5-HT3 antagonist, spasmolytics, anticholinergic, cholestyramine, anti-flatulence agents, metoclopramide, gastric-anti secretory agents (proton pump inhibitors; for indications other than Gastro esophageal Reflux Disease (GERD)), narcotics, anti-diarrheal drugs, and systemic steroids)
- Use of immunosuppressive or immunomodulatory medications (i.e., biologics), including oral or parenteral corticosteroids
- All opioids are prohibited unless for occasional rescue medication purposes. In case of uncertainty regarding prohibited medications please contact the medical monitor.

Concomitant medications taken during washout period were documented in the source data.

Note: This list of drugs was not exhaustive. However, any drug which was not mentioned above and having a possible on study drug efficacy and safety, was confirmed with medical monitor or medical expert.

8.3.3. Treatment compliance

Being a retrospective study, only the subject records with all data is considered to maintain the treatment compliance.

9. EFFICACY VARIABLES

9.1. Efficacy Measurements Assessed

9.1.1. Efficacy measurement:

The primary efficacy endpoint for this study was the effectiveness of Petshuddhi Churna in decreasing constipation Symptoms along with the following:

- Differences in Abdominal Discomfort measured on 10 point scale[0-9]
- Change in stool consistency with 5 point scale[1-5]
- Number of patients with complete defecation.

9.1.2. Description of Data Capture

1) Demographic data, body weight and body height.
2) Abdomen Discomfort
3) Completeness Bowel Movement, and Stool Consistency
4) Appropriateness of measurements

The efficacy assessments performed in the study were considered as medical standard and were widely used in comparable studies with the objective to determine the effect of a therapeutic intervention in Constipation.

9.1.3. Primary Efficacy Variable(s)

The primary efficacy endpoint was effectiveness of Petshuddhi Churna in decreasing constipation Symptoms from baseline to day 30.

- Differences in abdominal discomfort over the study period from the baseline to day 30
- Differences in Stool Consistency from the baseline to day 30
- Differences in number of subjects with a feeling of incomplete defecation the study period from the baseline to day 30

9.1.4. Drug Concentration Measurements:

Not applicable

9.2. Data Quality Assurance

The Quality Assurance department of MGCTS conducted site audits to check the compliance of study conduct with the Protocol, SOPs and applicable regulatory requirements.

The clinical raw data generated during the study at site was reviewed by monitor(s) and QA personnel. During the QA audit visit clinical raw data such as source data and other related records were audited retrospectively to assess the adherence of the activities and reported data to the applicable SOPs and the Protocol.

The clinical and biostatistics raw data such as Database extract, NCSS Output and NCSS Summary Report and other related data were audited retrospectively to assess the adherence of the activities and reported data to the applicable SOPs and the Protocol.

The observations noted during the audit of the various phases were compiled and sent to the concerned personnel of the respective departments. The concerns were discussed and followed up until resolution. Upon resolution of all concerns / issues, the Quality Assurance Authentication was issued.

9.3. Statistical Methods Planned in the Protocol and Determination of Sample Size

9.3.1. Statistical and analytical plans

All statistical analysis was done using NCSS V 11.0 or higher.

For continuous variables, the summary statistics was the number of observations, mean, standard deviation, median, minimum and maximum values. Categorical values were summarized using frequencies and percentages.

9.3.2. Primary Efficacy Endpoint:

The primary endpoint was analyzed using an analysis of covariance (ANCOVA) model with change in score from baseline as a response variable, treatment as fixed effects, and baseline score as a covariate.

For the primary efficacy, 95% confidence interval for the difference of means (μT-μR) between the test and Placebo products was constructed for PP population.

9.3.3. Determination of sample size

P0P1	Alpha	Beta	Cut-Off R + 1	N	Actual Alpha	Actual Beta	
0.035	0.200	0.010	0.050	6	100	0.008	0.048

References

A'Hern, R. P. A. 2001. 'Sample size tables for exact single-stage phase II designs.' Statistics in Medicine,
Volume 20, pages 859-866.

Fleming, T. R. 1982. 'One-sample multiple testing procedure for Phase II clinical trials.' Biometrics, Volume

38, pages 143-151.

Report Definitions

P0 is the maximum response proportion of a poor drug.

P1 is the minimum response proportion of a good drug.

N is the sample size.

If the number of responses ≥ R+1, P0 is rejected.

If the number of responses ≤ R, P1 is rejected.

Alpha is the probability of rejecting that P ≤ P0 when this is true.

Beta is the probability of rejecting that P ≥ P1 when this is true.

Summary Statements

A study requires 100 subjects to decide whether the proportion responding, P, is less than or equal to 0.035 or greater than or equal to 0.200. If the number of responses is 6 or more, the hypothesis that P ≤ 0.035 is rejected with a target error rate of 0.010 and an actual error rate of 0.008. If the number of responses is 5 or less, the hypothesis that P ≥ 0.200 is rejected with a target error rate of 0.050 and an actual error rate of 0.048.

Dropout-Inflated Sample Size

Dropout Rate	Sample Size N	Dropout-Inflated Enrollment Sample Size N'	Expected Number of Dropouts D
00%	100	100	00

Definitions

Dropout Rate (DR) is the percentage of subjects (or items) that are expected to be lost at random during the course of the study and for whom no response data will be collected (i.e. will be treated as "missing").

N is the evaluable sample size at which power is computed. If N subjects are evaluated out of the N' subjects that are enrolled in the study, the design will achieve the stated power.

N' is the total number of subjects that should be enrolled in the study in order to end up with N

Evaluable subjects, based on the assumed dropout rate. After solving for N, N' is calculated by inflating N using the formula N' = N / (1 - DR), with N' always rounded up. (See Julious, S.A. (2010) pages 52-53, or Chow, S.C.,

Shao, J., and Wang, H. (2008) pages 39-40.)

D is the expected number of dropouts. D = N' - N.

Power (Probability of Rejecting $P \leq P0$ when $P \geq P1$): 0.95

Alpha (Probability of Rejecting $P \leq P0$ when $P \leq P0$): 0.01

P0 (Maximum Response Rate of a Poor Treatment): 0.035

P1 (Minimum Response Rate of a Good Treatment): 0.2

9.4. Changes in the Conduct of Study or Planned Analyses

The study was conducted as per IEC approved protocol, errata 01 of protocol and all the related study plans. There was no change in the design and conduct of the study.

10. STUDY PATIENTS

10.1. Disposition of Patients

Out of the 115 patient records that were screened, 100 were selected as per the inclusion & exclusion criteria with complete data to analyze. The PP population included all the completers with no major protocol violations that would affect the treatment evaluation (Test product N=100).

Table 1: List of Patients Disposition

Parameters	**No. of cases**
Total no. of patients records identified	115
Total no. of patients dropped out due to non-compliance	15
No. of patients included	100
No. of patients in Treatment group	100

10.2. Protocol Deviations

No protocol deviations were reported during the study conduct.

11. EFFICACY EVALUATION

11.1. Data Sets Analyzed

All included patients (N=100) who have received all 30 days dosage of study drug were considered for the efficacy assessment. The PP population (N=100) that was used for the main analysis of the primary endpoint with no major deviations that would affect the treatment evaluation.

11.2. Demographic and Other Baseline Characteristics

A total of 100 patient records were considered into the study. Weight, BMI, height and age of each patient were recorded during screening.

Table2: Demographic profile

Parameters	**Treatment Group (N = 100)**
@Age (Yrs.)	
Mean	38.16
SD	11.77
Range	20 – 65
#Gender (%)	
Male	50 (50.0)
Female	50 (50.0)
@Height (CM)	
Mean	162.61
SD	11.47
Range	121.92 – 179.83
@Weight (Kg)	
Mean	60.39

SD Range	9.01 33.5 – 5.00
@BMI Mean SD Range	 22.93 3.599 17.91 – 41.04

Above data shows that age of the cases in this study ranged from 20 to 65 years. Among the cases in the treatment group, the average age was 38.16 years.

50% of the cases among the treatment group were males and 50% of the cases among the treatment group were females.

Average height of the patients among treatment group was 162.61cm. Average weight of the patients among treatment group was 60.39 Kg.

Mean BMI of the patients among treatment group was 22.93 Kg/m^2.

Note: The PP population included all patients who met all inclusion/exclusion criteria and did not have any major protocol violation that was affect the treatment evaluation.

12. EFFICACY RESULTS AND TABULATIONS OF PATIENT DATA

12.1. KEY EFFICACY ASSESSMENTS

Table 3: Changes in Complete Spontaneous Bowel Movement (Complete Defecation)

Visit	**Treatment Group (N = 100)**	
	Yes (%)	**No (%)**
Baseline (Visit 1)	8 (8)	92 (92)
Visit 2	84 (84)	16 (16)
P values (Baseline vs. Visit 2)	<0.001	

By Chi-square test, p <0.05 Significant

8% of the cases among the treatment group at baseline had complete spontaneous

bowel movement. After 30 days of treatment 84% of the cases among treatment group complete spontaneous bowel movement.

Clinically significant improvement was observed among the test cases.

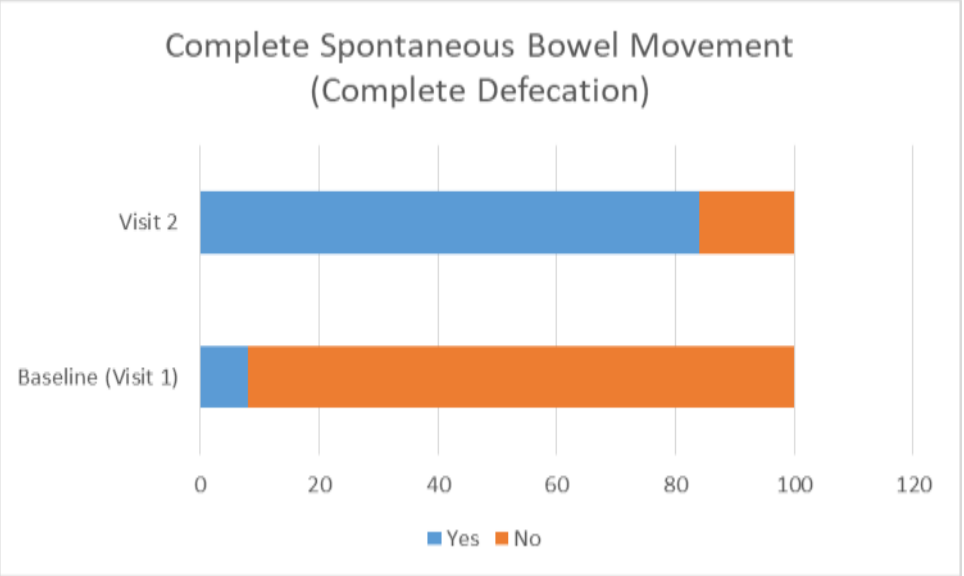


Figure 1: Changes in Complete Spontaneous Bowel Movement

Table5: Mean Change in Patient Assessment of Abdominal Discomfort

Visit	**Treatment Group (N = 100)**
Baseline (Visit 1)	4.92
Visit 2	1.42
P values (Baseline vs. Visit 2)	<0.001

By t test, p <0.05 Significant

As per this data average abdominal discomfort score at baseline among the treatment group was 4.92 which was indicative of Medium abdominal discomfort. After 30 days of treatment the abdominal discomfort score among the treatment group was 1.42 showing clinically significant improvement in the abdominal discomfort when compared to the baseline.

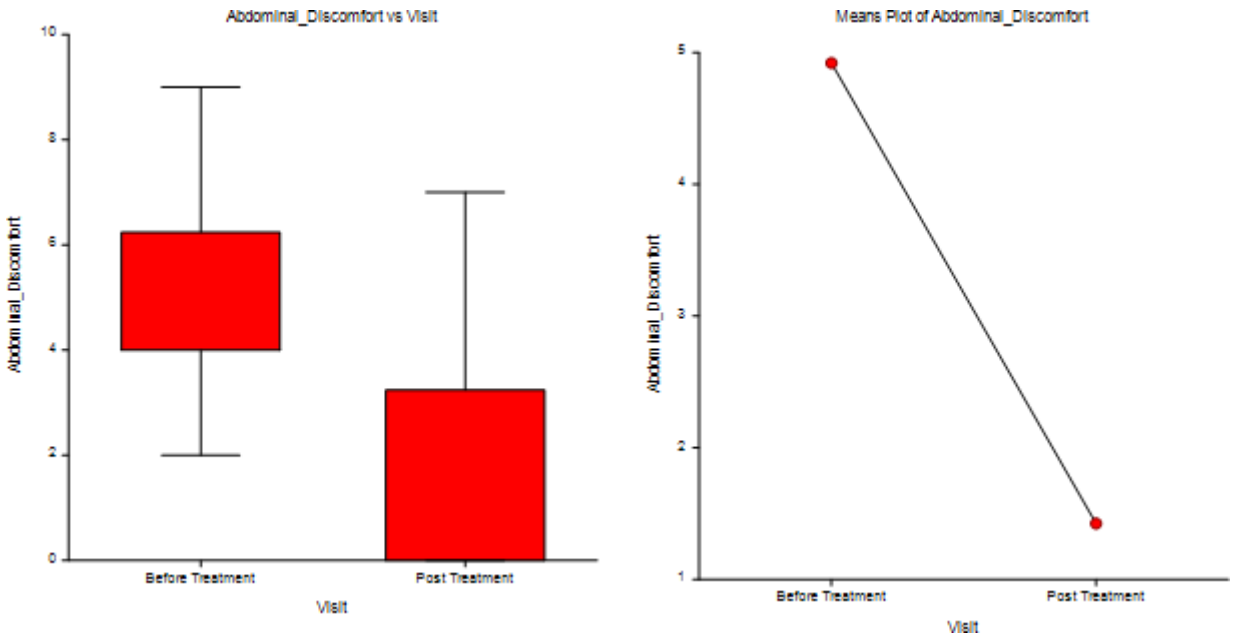


Figure 3: Mean Change in Patient Assessment of Abdominal Discomfort

Table6: Mean Change in Stool Consistency score

Visit	**Treatment Group (N = 100)**
Baseline (Visit 1)	1.78
Visit 2	2.90
P values (Baseline vs. Visit 2)	<0.001

By t test, p <0.05 Significant

The study shows that average stool consistency score at baseline among the treatment group was 1.78 which was indicative of stool consistency like a sausage with cracks. After 30 days of treatment the mean stool consistency score among the treatment group was 2.90 which was indicative of stool consistency like a sausage but crumby and smoother on the surface which was significant from the baseline.

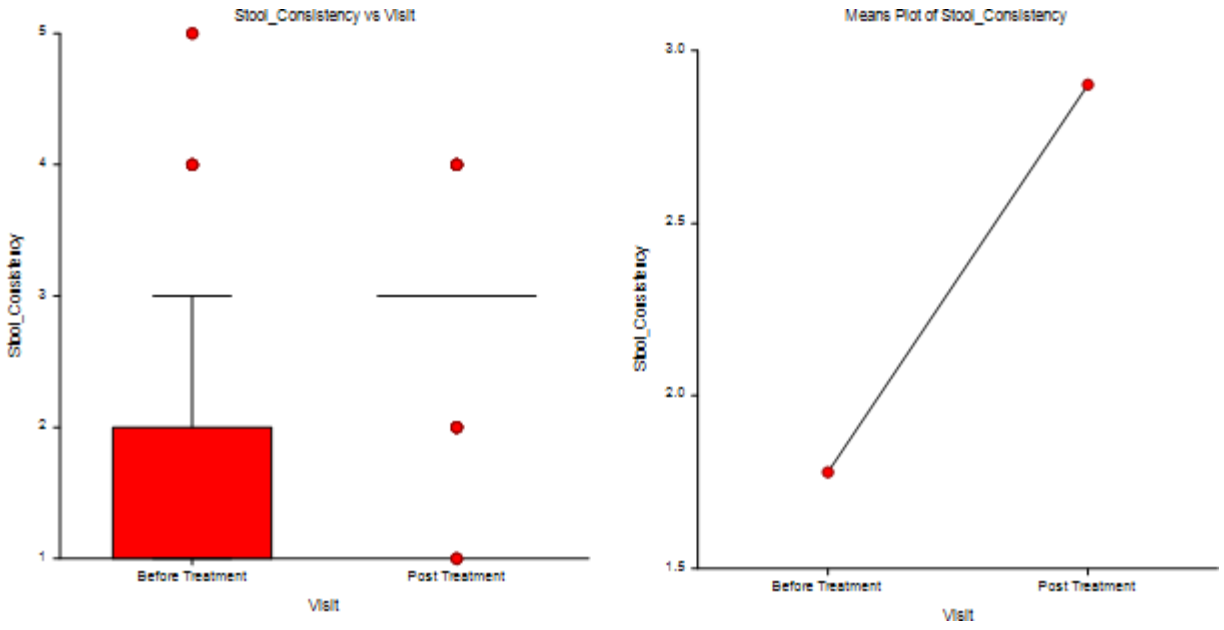


Figure 4: Mean Change in Stool consistency score

13. SAFETY EVALUATION

13.1. Extent of Exposure

In this study, a total of 100 patients were under treatment with Petshuddhi Churna, 1 tsp daily at bedtime, for 30 days.

The total duration was 30 days for the test product,

Total no. of patient exposed with Test Product: 100

13.2. Adverse Events

There was no treatment emergent adverse events were reported.

There was no laboratory change considered to be a serious adverse event or another significant adverse event.

13.3. Clinical Laboratory Evaluation

Clinical laboratory tests were recorded at Visit 1 and Visit 2 of study.

13.4. Safety Conclusions

No treatment emergent adverse events were reported. No death, serious or severe adverse events were reported during the conduct of the study.
There was no laboratory change considered to be a serious adverse event or another significant adverse event.

14. DISCUSSION AND OVERALL CONCLUSIONS

This clinical study report describes the methods and results of study MGCTSR6, a retrospective study to assess the effectiveness of Petshuddhi Churna in the treatment of Constipation.

The primary endpoint: The primary efficacy endpoint for the study was chosen as the change in the constipation symptoms measured as change in abdominal discomfort, stool consistency and feeling of incomplete defecation.

Overall, a total of One Hundred Fifteen (115) patient records were screened in the study of which hundred (100) patient records completed the study as per protocol. Fifteen (15) patient records were not considered as they were not incompliance with the inclusion & Exclusion Criteria.

Main analysis was performed within the PP population which was comprised of 100 patient records who received the test product Petshuddhi Churna. Analysis was performed using an ANOVA model with NCSS.

14.1. Discussion on Efficacy results:

1. Age of the cases in this study ranged from 20 to 65 years with average age 38.16 years among treatment group. 50% of the cases among the treatment group were male and 50% female.
2. Average BMI of the patients among treatment group was 22.93 Kg/m^2.
3. Complete Spontaneous Bowel Movement: 8% of the cases among the treatment group at baseline had complete spontaneous bowel movement. After 30 days of treatment 84% of the cases among treatment group complete spontaneous bowel movement. This indicates that Petshuddhi Churna helps in complete defecation.
4. Average abdominal discomfort score at baseline among the treatment group was 4.92 which was indicative of Medium abdominal discomfort. After 30 days of

treatment the abdominal discomfort score among the treatment group was 1.42 showing clinically significant improvement in the abdominal discomfort when compared to the baseline. This indicates that the abdominal discomfort reduces to a good level when used for 30 days regularly.

5. Average stool consistency score at baseline among the treatment group was 1.78 which was indicative of stool consistency like a sausage with cracks. After 30 days of treatment the mean stool consistency score among the treatment group was 2.90 which was indicative of stool consistency like a sausage but crumby and smooth on the surface which was significant from the baseline. This indicates that that stool consistency gets better when you use Petshuddhi Churna for 30 days.

14.2. Discussion on Safety Results:

The test and reference product were well tolerated by the patients.

No adverse event was reported during the study.

All the vital signs were found normal at baseline and the end visit.

Concomitant medications were allowed only for Fever or any physical injury during the study treatment period on SOS basis apart from the ones subjects take as their routine prior medication.

There were no protocol violations and deviations reported.

No death, serious or severe adverse events were reported during the conduct of the study.

14.3. Overall Conclusion:

Petshuddhi Churna was effective in maintaining and treating the constipation symptoms. In conclusion, there was significant change from the baseline till the end of the treatment among most of the efficacy parameters observed.

Petshuddhi Churna was effective in maintaining and treating the constipation symptoms, such as Complete spontaneous Bowel Movement, Abdominal Discomfort and Stool Consistency. No adverse events were reported by the patients after using Petshuddhi Churna indicating that it was well tolerated and thus safe to use.

15. REFERENCES

1. Dross man DA, Corazziari E, Delvaux N, Spiller R, Talley NJ, Thompson CA, et al. Rome III: The functional gastrointestinal disorders. 3 ed. McLean, VA: Degnon Associates; 2006.

2. Thompson WG. Constipation: pathogenesis and management. Lancet 1993 Jun 19; 341(8860):1569-72.

3. Lynn RB, Friedman LS. Constipation. N Engl J Med 1993 Dec 23; 329(26):1940-5.

4. Zighelboim J, Talley NJ. What are functional bowel disorders? Gastroenterology 1993 Apr; 104(4):1196-201.

Appendix:

Statistical Analysis

One-Way Analysis of Variance Report

Dataset Untitled
Response Abdominal_Discomfort

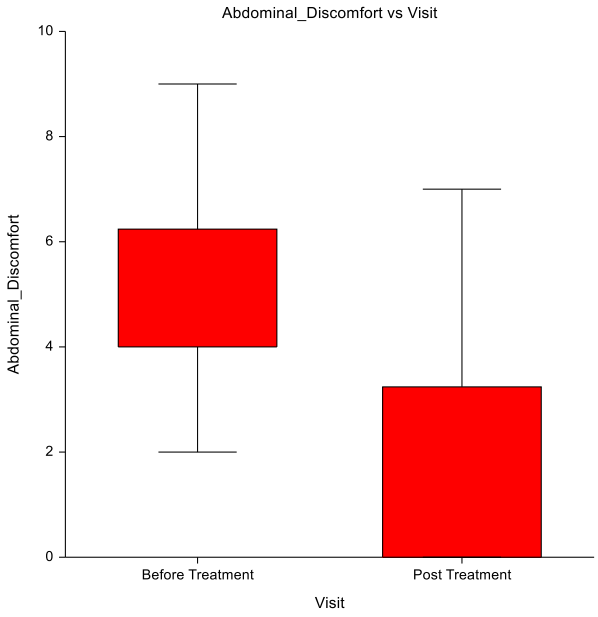
Tests of the Normality of Residuals Assumption

Normality Attributes	Test Value	Prob Level	Reject Normality? (α=0.20)
Skewness	3.9823	0.00007	Yes
Kurtosis	0.0843	0.93284	No
Skewness and Kurtosis (Omnibus)	15.8661	0.00036	Yes

Tests of the Equality of Group Variances Assumption

Test Name	Test Value	Prob Level	Reject Equal Variances? (α=0.20)
Brown-Forsythe (Data - Medians)	0.4693	0.49492	No
Levene (Data - Means)	4.1703	0.04382	Yes
Conover (Ranks of Deviations)	6.4002	0.01141	Yes
Bartlett (Likelihood Ratio)	3.1328	0.07673	Yes

Box Plot Section



One-Way Analysis of Variance Report

Dataset Untitled
Response Abdominal_Discomfort

Expected Mean Squares Table

Model Term	DF	Term Fixed?	Denominator Term	Expected Mean Square
A: Visit	1	Yes	σ^2	$\sigma^2 + sA$
Error	98	No		σ^2

Note: Expected Mean Squares are for the balanced cell-frequency case.

Analysis of Variance Table and F-Test

Model Term	DF	Sum of Squares	Mean Square	F-Ratio	Prob Level	Reject Equal Means? (α=0.05)	Power (α=0.05)
Between (Visit)	1	306.25	306.25	79.4276	0.00000	Yes	1.00000
Within (Error)	98	377.86	3.855714				
Adjusted Total	99	684.11					
Total	100						

Welch's Test of Means Allowing for Unequal Variances

Model Term	Numerator DF	Denominator DF	F-Ratio	Prob Level	Reject Equal Means? (α=0.05)
Between Groups	1	92.23	79.4276	0.00000	Yes

Kruskal-Wallis One-Way ANOVA on Ranks

Hypotheses
H0: All medians are equal.
H1: At least two medians are different.

Test Results

Method	DF	Chi-Squared (H)	Prob Level	Reject H0? (α=0.05)
Not Corrected for Ties	1	36.5527	0.00000	Yes
Corrected for Ties	1	38.9268	0.00000	Yes

Number Sets of Ties	9
Multiplicity Factor	60984

Group Detail

Group	Count	Sum of Ranks	Mean Rank	Z-Value	Median
Before Treatment	100	3402.00	68.04	6.0459	4
Post Treatment	100	1648.00	32.96	-6.0459	0

One-Way Analysis of Variance Report

Dataset Untitled
Response Abdominal_Discomfort

Normal Scores Tests

Hypotheses
H0: All group data distributions are the same.
H1: At least one group has observations that tend to be greater than those of the other groups.

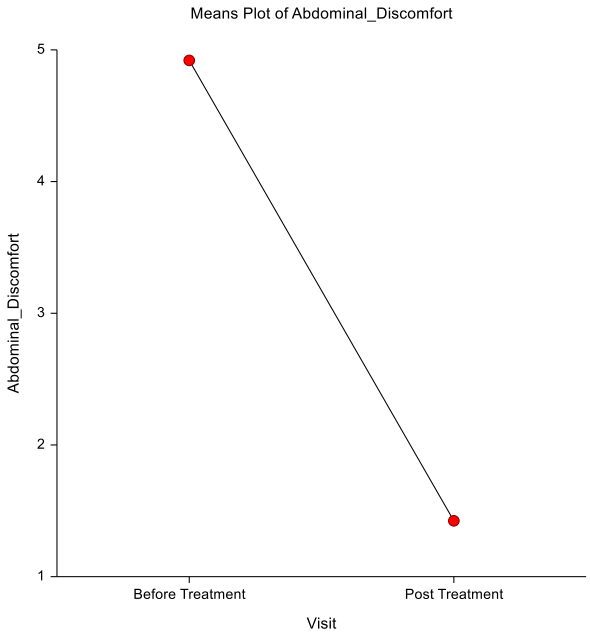
Results

Test	DF	Chi-Squared (H)	Prob Level	Reject H0? (α=0.20)
Terry-Hoeffding - Expected Normal Scores	1	38.5699	0.00000	Yes
Van der Waerden - Normal Quantiles	1	38.6499	0.00000	Yes

Descriptive Statistics

Group	Count (ni)	Mean	Effect	Median	Standard Deviation	Standard Error √(MSE/ni)
All	200	3.17	3.17			
A: Visit						
Before Treatment	100	4.92	1.75	4	1.70042	0.2776946
Post Treatment	100	1.42	-1.75	0	2.19545	0.2776946

Plots of Means Section



One-Way Analysis of Variance Report

Dataset Untitled
Response Complete_Bowel_Movement

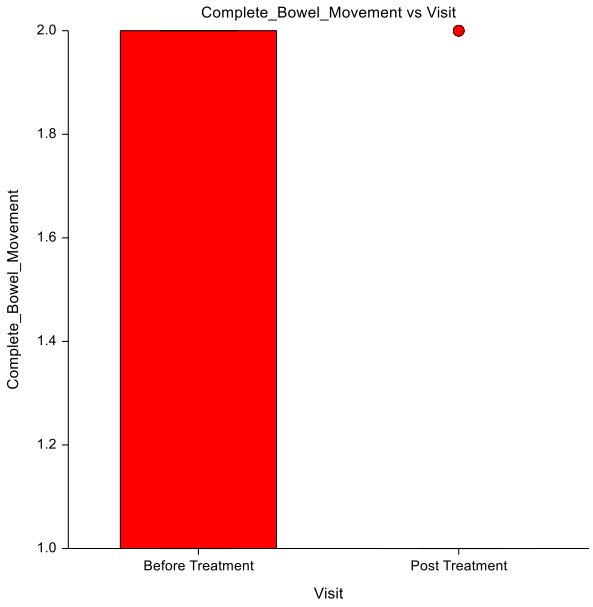
Tests of the Normality of Residuals Assumption

Normality Attributes	Test Value	Prob Level	Reject Normality? (α=0.20)
Skewness	-0.1297	0.89677	No
Kurtosis	0.3407	0.73335	No
Skewness and Kurtosis (Omnibus)	0.1329	0.93571	No

Tests of the Equality of Group Variances Assumption

Test Name	Test Value	Prob Level	Reject Equal Variances? (α=0.20)
Brown-Forsythe (Data - Medians)	5.0304	0.02716	Yes
Levene (Data - Means)	22.5835	0.00001	Yes
Conover (Ranks of Deviations)	32.8555	0.00000	Yes
Bartlett (Likelihood Ratio)	5.6213	0.01774	Yes

Box Plot Section



One-Way Analysis of Variance Report

Dataset Untitled
Response Complete_Bowel_Movement

Expected Mean Squares Table

Model Term	DF	Term Fixed?	Denominator Term	Expected Mean Square
A: Visit	1	Yes	σ^2	$\sigma^2 + sA$
Error	98	No		σ^2

Note: Expected Mean Squares are for the balanced cell-frequency case.

Analysis of Variance Table and F-Test

Model Term	DF	Sum of Squares	Mean Square	F-Ratio	Prob Level	Reject Equal Means? (α=0.05)	Power (α=0.05)
Between (Visit)	1	8.41	8.41	52.2294	0.00000	Yes	1.00000
Within (Error)	98	15.78	0.1610204				
Adjusted Total	99	24.19					
Total	100						

Welch's Test of Means Allowing for Unequal Variances

Model Term	Numerator DF	Denominator DF	F-Ratio	Prob Level	Reject Equal Means? (α=0.05)
Between Groups	1	88.33	52.2294	0.00000	Yes

Kruskal-Wallis One-Way ANOVA on Ranks

Hypotheses
H0: All medians are equal.
H1: At least two medians are different.

Test Results

Method	DF	Chi-Squared (H)	Prob Level	Reject H0? (α=0.05)
Not Corrected for Ties	1	24.9802	0.00000	Yes
Corrected for Ties	1	34.4188	0.00000	Yes

Number Sets of Ties	2
Multiplicity Factor	274200

Group Detail

Group	Count	Sum of Ranks	Mean Rank	Z-Value	Median
Before Treatment	100	3250.00	65.00	4.9980	2
Post Treatment	100	1800.00	36.00	-4.9980	1

One-Way Analysis of Variance Report

Dataset Untitled
Response Complete_Bowel_Movement

Normal Scores Tests

Hypotheses
H0: All group data distributions are the same.
H1: At least one group has observations that tend to be greater than those of the other groups.

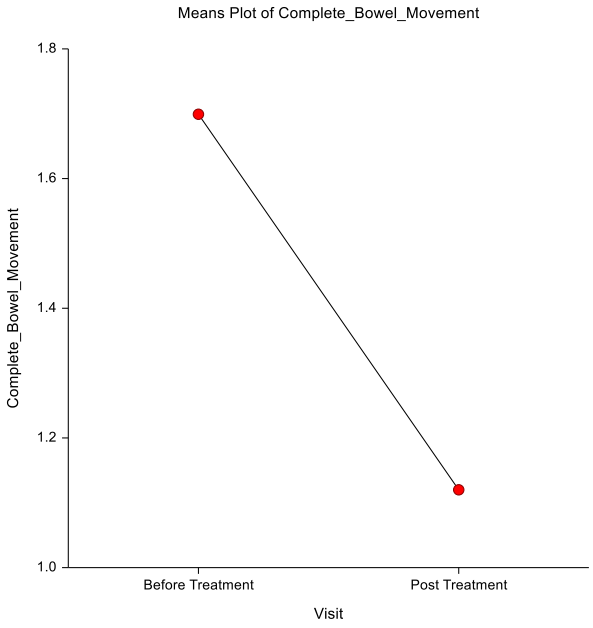
Results

Test	DF	Chi-Squared (H)	Prob Level	Reject H0? (α=0.20)
Terry-Hoeffding - Expected Normal Scores	1	34.4188	0.00000	Yes
Van der Waerden - Normal Quantiles	1	34.4188	0.00000	Yes

Descriptive Statistics

Group	Count (ni)	Mean	Effect	Median	Standard Deviation	Standard Error √(MSE/ni)
All	200	1.41	1.41			
A: Visit						
Before Treatment	100	1.7	0.29	2	0.4629101	0.05674864
Post Treatment	100	1.12	-0.29	1	0.3282607	0.05674864

Plots of Means Section



One-Way Analysis of Variance Report

Dataset Untitled
Response Stool_Consistency

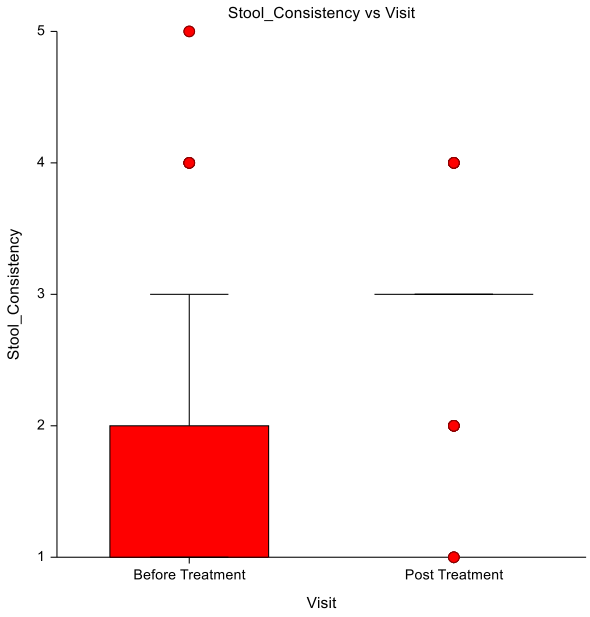
Tests of the Normality of Residuals Assumption

Normality Attributes	Test Value	Prob Level	Reject Normality? (α=0.20)
Skewness	3.9317	0.00008	Yes
Kurtosis	2.4578	0.01398	Yes
Skewness and Kurtosis (Omnibus)	21.4989	0.00002	Yes

Tests of the Equality of Group Variances Assumption

Test Name	Test Value	Prob Level	Reject Equal Variances? (α=0.20)
Brown-Forsythe (Data - Medians)	4.4364	0.03774	Yes
Levene (Data - Means)	17.4426	0.00006	Yes
Conover (Ranks of Deviations)	9.9313	0.00162	Yes
Bartlett (Likelihood Ratio)	12.9859	0.00031	Yes

Box Plot Section



One-Way Analysis of Variance Report

Dataset Untitled
Response Stool_Consistency

Expected Mean Squares Table

Model Term	DF	Term Fixed?	Denominator Term	Expected Mean Square
A: Visit	1	Yes	σ^2	$\sigma^2 + sA$
Error	98	No		σ^2

Note: Expected Mean Squares are for the balanced cell-frequency case.

Analysis of Variance Table and F-Test

Model Term	DF	Sum of Squares	Mean Square	F-Ratio	Prob Level	Reject Equal Means? (α=0.05)	Power (α=0.05)
Between (Visit)	1	31.36	31.36	32.3231	0.00000	Yes	0.99988
Within (Error)	98	95.08	0.9702041				
Adjusted Total	99	126.44					
Total	100						

Welch's Test of Means Allowing for Unequal Variances

Model Term	Numerator DF	Denominator DF	F-Ratio	Prob Level	Reject Equal Means? (α=0.05)
Between Groups	1	79.36	32.3231	0.00000	Yes

Kruskal-Wallis One-Way ANOVA on Ranks

Hypotheses
H0: All medians are equal.
H1: At least two medians are different.

Test Results

Method	DF	Chi-Squared (H)	Prob Level	Reject H0? (α=0.05)
Not Corrected for Ties	1	24.5684	0.00000	Yes
Corrected for Ties	1	27.2548	0.00000	Yes

Number Sets of Ties	5
Multiplicity Factor	98556

Group Detail

Group	Count	Sum of Ranks	Mean Rank	Z-Value	Median
Before Treatment	100	1806.00	36.12	-4.9567	1
Post Treatment	100	3244.00	64.88	4.9567	3

One-Way Analysis of Variance Report

Dataset Untitled
Response Stool_Consistency

Normal Scores Tests

Hypotheses
H0: All group data distributions are the same.
H1: At least one group has observations that tend to be greater than those of the other groups.

Results

Test	DF	Chi-Squared (H)	Prob Level	Reject H0? (α=0.20)
Terry-Hoeffding - Expected Normal Scores	1	21.3680	0.00000	Yes
Van der Waerden - Normal Quantiles	1	21.8530	0.00000	Yes

Descriptive Statistics

Group	Count (ni)	Mean	Effect	Median	Standard Deviation	Standard Error √(MSE/ni)
All	200	2.34	2.34			
A: Visit						
Before Treatment	100	1.78	-0.56	1	1.20017	0.1392985
Post Treatment	100	2.9	0.56	3	0.7071068	0.1392985

Plots of Means Section