International Journal of Current Advanced Research
ISSN: O: 2319-6475, ISSN: P: 2319-6505, Impact Factor: 6.614
Available Online at www.journalijcar.org
Volume 10; Issue 08 (C); August 2021; Page No.25066-25068
DOI: http://dx.doi.org/10.24327/ijcar.2021.25068.5002

Research Article

EVALUATION OF EFFICACY & SAFETY OF TWO SIDDHA FORMULATIONS FOR THE TREATMENT OF FUNCTIONAL CONSTIPATION - STRUCTURED SUMMARY OF A STUDY PROTOCOL - A COMPARATIVE RANDOMIZED CLINICAL TRIAL

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A R T I C L E I N F O

Article History:
Received 4th May, 2021
Received in revised form 25th June, 2021
Accepted 18th July, 2021
Published online 28th August, 2021

Key words:

Randomised Controlled Trial, Protocol, Siddha Medicine, Functional Constipation, CAM,

A B S T R A C T

Objectives: The primary objectives of this trial are to evaluate the efficacy of the Sivathai Chooranam to compared with Nilavarai Chooranam in the management of Functional Constipation. This study is to explore the best proven Siddha treatment for the Management of functional constipation. The secondary objectives are to evaluate the safety of the Sivathai Chooranam and Nilavarai Chooranam on Functional Constipation and evaluate the patient quality of life using the PAC-QOL (patient assessment of constipation quality of life questionnaire. **Trial Design:** An open Labelled, Double arm, Single Centre, Exploratory and comparative Randomized Controlled Trial. **Participants:** Patients who Clinically confirmed Functional Constipation at Siddha Clinical Research Unit, New Delhi – OPD , both sexes aged 18-65, willing and consenting to participate will be recruited into the study. **Main Outcomes: Primary outcomes: (21 Days)** 30 % increase of Participant's Bowel movement will be expected after completion of study **which will be measured by** *Bristol stool Formation Scale and Modified Longo Score* **Randomisation:** Randomization will be done following Simple randomization method. The Participants will be assigned into 2 Groups and will be allocated in 1:1 Ratio in each group through randomization blocks in Microsoft Excel by a Statistician after the assessment of eligibility and Informed consent procedures. **Blinding:** The Study is an open labelled. Participants and Investigators will not be blinded. **Trial Status:** Protocol Number: SCRU Constipation Study 1, Version: 6.0 Protocol Date: 01.03.2021.The Trial started its recruitment on 27.02.2021.We anticipate study including data analysis will finish in Aug 2021 with in a period of 3 months. **Trial Registration:** This trial was registered with (Clinical Trial Registry of India) CTRI and the registration number is CTRI/2019/02/017831

INTRODUCTION

The primary objectives of this trial are to evaluate the efficacy of the Sivathai Chooranam to compared with Nilavarai Chooranam in the management of Functional Constipation. This study is to explore the best proven Siddha treatment for the Management of functional constipation.

The secondary objectives are to evaluate the safety of the Sivathai Chooranam and Nilavarai Chooranam on Functional Constipation and evaluate the patient quality of life using the PAC-QOL (patient assessment of constipation qualityof life questionnaire.

Trial Design

An open Labelled, Double arm, Single Centre, Exploratory and comparative Randomized Controlled Trial

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Participants

Patients who Clinically confirmed Functional Constipation at Siddha Clinical Research Unit, New Delhi – OPD, both sexes aged 18-65, willing and consenting to participate will be recruited into the study.

Intervention and comparator

Arm I: Nilavarai Chooranam (Control Group): 2 gms of Nilavarai Chooranam will be given with required quantity of Honey OD at Night, After food, before Sleep.

Arm II: Sivathai Chooranam (Trial Group) 2 gms of Sivathai Chooranam will be given with required quantity of Honey OD at Night, After food, before Sleep.

The Medicine will be procured form CCRS Pharmacy/ Renowned GMP Certified Siddha Pharmacy. Agmark Certified honey will be given along with Medicine to trial participants.

The investigational drugs are registered products under the Govt. of India and bought from GMP Certified Siddha Pharmacy.

Main Outcomes

Primary outcomes: (21 Days)

30 % increase of Participant's Bowel movement will be expected after completion of study which will be measured by *Bristol stool Formation Scale and Modified Longo Score*

Randomisation

Randomization will be done following Simple randomization method. The Participants will be assigned into 2 Groups and will be allocated in 1:1 Ratio in each group through randomization blocks in Microsoft Excel by a Statistician after the assessment of eligibility and Informed consent procedures.

Blinding: The Study is an open labelled. Participants and Investigators will not be blinded.

Numbers to Be Randomized (Sample Size): The design of the drug trial is exploratory in nature. Though a randomized selection of patients will be done to either of the two arms, the sample size is that of convenience and the same is not statistically powered however, sample size (30 patients in each arm) is sufficient to draw meaningful conclusions. The statistical significance $p<0.05$(two sided) is predefined for analysis. Statistical analysis will be performed using standard tests to compare the two interventional arms for primary and secondary efficacy measures. Safety events will be also analyzed. Both intent-to-treat and per protocol completer analysis will be performed. Regression analysis will be done to identify predictors of response. Clinical symptoms, Subjective parameters and Laboratory parameters will be subjected to Univariate and multivariate analysis using Statistical Package for Social Sciences (SPSS) 15.0 version with appropriate statistical methods.

A total Number of 60 Patients, 30 each in 2 groups will be recruited in 1:1 Ratio.

Statistical Method: Socio demographic and other anthropometric measures will be shown as descriptive statistics. Outcome of the measurement will be analysed by Student't' test. Level of significance will be arrived by use of – $P < 0.05$

Trial Status

Protocol Number: SCRU Constipation Study 1, Version: 6.0

Protocol Date: 01.03.2021

The Trial started its recruitment on 27.02.2021.We anticipate study including data analysis will finish in MAY 2021 with in a period of 3 months.

Trial Registration: This trial was registered with (Clinical Trial Registry of India) CTRI and the registration number is CTRI/2019/02/017831

Full Protocol: In the interest in expediting dissemination of this material, the usual familiar formatting has been eliminated. This letter serves as a summary and outline of the key elements of the full protocol. The Study protocol has been reported in accordance with the SPIRIT guidelines.

Acknowledgements

1. Prof.Dr.Ramasamy, Director General, Central Council for Research in India, Chennai.
2. Prof.Dr. Jugal Kishore, Director, HOD- Department of Community Medicine, VMMCH & Safdarjung Hospital, New Delhi.
3. Dr.P. Sathyarajeshwaran, Director- in-Charge, Siddha Central Research Institute, Central Council for Research in Siddha, Chennai.

KK, JK and PS given their inputs to finalize the Study Protocol.

Authors Contribution

MR conceived the study. MR, AB, SM initiated the study at trial site. MR contributed to Protocol writing. This protocol read and approved by all authors.

Authors Information

MR, SM and AB possess the background of Siddha.

Funding

The Trial is funded by the Central Council for Research in Siddha (CCRS), Min. of AYUSH, Govt. of India.

Availability of Data and Materials

All participant data will be kept confidential and personal identifiers of the study participants will not be disclosed to the public. Only the Investigator will have access to the trial data. All the procedures will be carried out by adherence of the Good Clinical Practices (GCP). The monitor will have access to the study documents.

Ethics Approval and consent to participate

The trial received the ethical approval from the Institutional Ethical Committee of Siddha Clinical Research Unit, Safdarjung Hospital, New Delhi on 01.03.2018.

This is to state that the appropriate ethical committee approval was taken.

Written Consent will be taken from all eligible and willing participants before their participation into the trial.

Consent for Publication: Not Applicable.

Competing Interest: The authors declares that they have no competing interests.

Author Details

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How to cite this article:

Manickavasagam Rengaraju *et al* (2021) 'Evaluation of Efficacy & Safety of Two Siddha Formulations For The Treatment of Functional Constipation - Structured Summary of A Study Protocol - A Comparative Randomized Clinical Trial', *International Journal of Current Advanced Research,* 10(08), pp. 25066-25068.
DOI: http://dx.doi.org/10.24327/ijcar.2021.25068.5002

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