**Clinical Trial Details (PDF Generation Date :- Tue, 03 Jan 2023 05:38:47 GMT)**

CTRI Number Last Modified On

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| CTRI/2021/06/034353 [Registered on: 23/06/2021] - **Trial Registered Prospectively** | | |
| 18/06/2021 | | |
| Yes | | |
| Interventional | | |
| Drug Ayurveda | | |
| Randomized, Parallel Group Trial | | |
| To Study The Effect Of Shatavari Churna And Musali Churna (Powder)In Lactation insuficency. | | |
| Open Label Double Arm Comparative Clinical Study To Evaluate The Efficacy Of Shatavari Churna And Musali Churna In Stanya Kshaya. | | |
| **Secondary ID** | | **Identifier** |
| NOT APPLICABLE | | NIL |
| **Details of Principal Investigator** | | |
| **Name** | Dr Vidyavati Ranganata | |
| **Designation** | Post graduate scholar | |
| **Affiliation** | Sri Kalabyraveshwara Swamy Ayurvedic Medical College Hospital and research centre | |
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| **Name** | Dr Papiya Jana | |
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| **Affiliation** | SRI KALABYRAVESWARA SWAMY AYURVEDIC MEDICAL COLLEGE HOSPITAL AND RESEARCH CENTRE | |
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| **Details Contact Person (Public Query)** | | |
| **Name** | Dr Papiya Jana | |
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Post Graduate Thesis Type of Trial

Type of Study

Study Design

Public Title of Study

Scientific Title of Study

Secondary IDs if Any

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details Contact Person (Scientific Query)

Details Contact Person (Public Query)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
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| **Source of Monetary or Material Support** | | | | | | |
| **>** SKAMCH AND RC BENGALURU | | | | | | |
| **Primary Sponsor Details** | | | | | | |
| **Name** | | Dr Vidyavati Ranganata | | | | |
| **Address** | | Sri Kalabyraveshwara Swmay Ayurvedic College Hospital And Research Centre | | | | |
| **Type of Sponsor** | | Other [SELF SPONSORED] | | | | |
| **Name** | | | | **Address** | | |
| NIL | | | | NOT APPLICABLE | | |
| **List of Countries** | | | | | | |
| India | | | | | | |
| **Name of Principal Investigator** | **Name of Site** | | | **Site Address** | | **Phone/Fax/Email** |
| Dr Kiran M Goud | SKAMCH AND RC | | | Department of PG studies in Prasuti Tantra Evum Stree Roga Vijayanagar Bengaluru 560104 Bangalore KARNATAKA | | 9845109556  [kiranmgoud@yahoo.co.](mailto:kiranmgoud@yahoo.co) in |
| **Name of Committee** | **Approval Status** | | | **Date of Approval** | | **Is Independent Ethics Committee?** |
| SKAMCH RC | Approved | | | 27/02/2019 | | No |
| **Status** | | | | **Date** | | |
| Not Applicable | | | | No Date Specified | | |
| **Health Type** | | | | **Condition** | | |
| Patients | | | | Hypogalactia | | |
| **Type** | | | **Name** | | **Details** | |
| Intervention | | | Shatavari Churna | | Shatavari Churna Was Given Orally 3gm Twice Daily For 1 Month | |
| Comparator Agent | | | Musali Churna | | Musali Churna Was Given Orally 3gm Twice Daily For 1 Month | |
| **Inclusion Criteria** | | | | | | |
| **Age From** | | 18.00 Year(s) | | | | |
| **Age To** | | 35.00 Year(s) | | | | |
| **Gender** | | Female | | | | |
| **Details** | | Subjects from 5th day of delivery.<br/> Subjects diagnosed as having Stanya Kshaya.<br/> Primigravida and multigravida with age group of 18-35 years.<br/> | | | | |
| **Exclusion Criteria** | | | | | | |

Source of Monetary or Material Support

Primary Sponsor

Details of Secondary Sponsor

Countries of Recruitment

Sites of Study

Details of Ethics Committee

Regulatory Clearance Status from DCGI

Health Condition / Problems Studied

Intervention / Comparator Agent

Inclusion Criteria

Exclusion Criteria

|  |  |  |
| --- | --- | --- |
| **Details** | Pathologies of breast like, Breast engorgement, Cracked or sore nipples, Mastitis,  Flat or inverted nipples.  History of Breast abscess, trauma and surgery.  History of HIV, infections and other systemic disorders. | |
| Coin toss, Lottery, toss of dice, shuffling cards etc | | |
| Alternation | | |
| Open Label | | |
| **Outcome** | | **Timepoints** |
| Shatavari Churna Is More Effective Compared To Musali Churna In Stanya Kshaya. | | 60 DAYS |
| **Outcome** | | **Timepoints** |
| Shatavari Churna Is More Effective Conpared To Musali Churna In Stanya Alpata,Stanya Pramana And Weight Gain Of The Baby | | 60 days |
| **Total Sample Size=**40 **Sample Size from India=**40  **Final Enrollment numbers achieved (Total)=**Applicable only for Completed/Terminated trials  **Final Enrollment numbers achieved (India)=**Applicable only for Completed/Terminated trials | | |
| Phase 2 | | |
| 28/06/2021 | | |
| No Date Specified | | |
| **Years=**1 **Months=**5 **Days=**2 | | |
| Not Applicable | | |
| Not Yet Recruiting | | |
| Nil | | |
| According to Ayurveda, *Stanya* is the *upadhatu* of *Rasadhatu*.3 According to *Acharya Kashyapa* during pregnancy, the food ingested gets transformed into *Rasa* and *Rakta Dhatu* where some of these nourishes the body parts of fetus, some is for production of breast milk and some parts for the digestion or metabolism and remaining provides nourishment to the body. In the same way after delivery of fetus, the *Prasad bhaga* of  *ahara Rasa* collected in the breast immediately forms *stanya. Rasadhatu Kshaya* often leads to *Stanya Kshaya4*. The prevalence of *Stanyakshaya* is increasing ranging from 23-63% in western countries and 45-53% in India.  In Ayurveda many treatment modalities are explained for *Stanyakshaya* so, in present study *Shatavari Churna* and *Musali churna* are selected which is having properties like *Guru, Snigdha Guna, Sheeta Virya and* | | |

Method of Generating Random Sequence

Method of Concealment

Blinding/Masking Primary Outcome

Secondary Outcome

Target Sample Size

Phase of Trial

Date of First Enrollment (India)

Date of First Enrollment (Global)

Estimated Duration of Trial

Recruitment Status of Trial (Global)

Recruitment Status of Trial (India)

Publication Details Brief Summary

*Kaphavardhaka.*