Clinical Trial Details (PDF Generation Date :- Wed, 07 Jun 2023 16:35:01 GMT)

CTRI Number	CTRI/2017/05/008450 [Registered on: 02/05/2017] - **Trial Registered Prospectively**
Last Modified On	20/08/2018
Post Graduate Thesis	Yes
Type of Trial	Interventional
Type of Study	Homeopathy
Study Design	Randomized, Parallel Group, Placebo Controlled Trial
Public Title of Study	Homoeopathic treatment of sleeplessness
Scientific Title of Study	Efficacy of Individualized Homoeopathic Treatment of Insomnia; Double Blind, Randomized, Placebo Controlled Clinical Trial

Secondary IDs if Any

Secondary ID	Identifier
U1111-1195-7691	UTN

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

Details of Principal Investigator	
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Designation	Postgraduate Trainee
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Details Contact Person (Scientific Query)

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Source of Monetary or Material Support

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> National Institute of Homoeopathy, Ministry of AYUSH, Govt. of India; Block GE, Sector III, Salt Lake, Kolkata, West Bengal 700106, India

Primary Sponsor

Primary Sponsor Details	
Name	National Institute of Homoeopathy Ministry of AYUSH Govt of India
Address	Block GE, Sector III, Salt Lake, Kolkata, West Bengal 700106, India
Type of Sponsor	Government medical college

Details of Secondary Sponsor

Name	Address
NIL	NIL

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
James Michael	National Institute of Homoeopathy, Govt. of India	OPD 5, National Institute of Homoeopathy, Block GE, Sector III, Salt Lake, Kolkata, West Bengal 700106, India; Monday to Saturday, 9 am to 2 pm Kolkata WEST BENGAL	7044515049 jamesmichael312@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Institutional Ethics Committee	Approved	27/03/2017	No

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Patients	Insomnia

Intervention / Comparator Agent

Type	Name	Details
Intervention	Individualized homeopathic medicine in centesimal or 50 millesimal potencies	In centesimal potencies, each dose consisted of 4 cane sugar globules no. 30, moistened with a single drop of the indicated medicine, preserved in 90% v/v ethanol; repetition depending upon the individual requirement of the case and as per homeopathic principles. In 50 millesimal scale, a single medicated cane sugar globules of poppy seed size (no. 10) was dissolved in 90 ml of distilled water with addition of 2 drops of 90% v/v ethanol; 16 doses to be marked on the vial; each dose of 5 ml to be taken after 10 uniformly forceful downward strokes to the vial in 45 ml

		normal water in a clean cup, to stir well, to take 5 ml of this liquid orally, and to discard rest of the liquid from the cup. Each dose was directed to be taken orally on clean tongue with empty stomach. Duration of such therapy was 3 months.
Comparator Agent	Placebo	Each dose in centesimal scale consisted of 4 cane sugar globules no. 30, moistened with a single drop of rectified spirit; identical in appearance with and indistinguishable from the medicine. In 50 millesimal scale, a single non-medicated cane sugar globules of poppy seed size (no. 10) was dissolved in 90 ml of distilled water with addition of 2 drops of 90% v/v ethanol; 16 doses to be marked on the vial; each dose of 5 ml to be taken after 10 uniformly forceful downward strokes to the vial in 45 ml normal water in a clean cup, to stir well, to take 5 ml of this liquid orally, and to discard rest of the liquid from the cup. Dosage and instructions were same as in the intervention arm. Each dose was directed to be taken orally on clean tongue with empty stomach. Duration of therapy was 3 months.

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	65.00 Year(s)
Gender	Both
Details	1. Both male and female patients 2. Age between 18 and 65 years 3. Patients with known but controlled systemic diseases 4. Patients giving written consent to participate

Exclusion Criteria

Exclusion Criteria	
Details	1. Cases suffering from uncontrolled systemic illness or life-threatening infections 2. Cases already undergoing homoeopathic treatment elsewhere for any chronic disease 3. Self-reported immune-compromised state 4. Substance abuse and/or dependence 5. Pregnant or lactating women 6. Patients with psychiatric diseases

Method of Generating Random Sequence	Computer generated randomization
Method of Concealment	Pharmacy-controlled Randomization
Blinding/Masking	Participant and Investigator Blinded

Primary Outcome

Outcome	Timepoints

	Sleep diary	3 months

Secondary Outcome

Outcome	Timepoints
Insomnia Severity Index (ISI) questionnaire	3 months

Target Sample Size	**Total Sample Size=**60 **Sample Size from India=**60 **Final Enrollment numbers achieved (Total)=**60 **Final Enrollment numbers achieved (India)=**60
Phase of Trial	Phase 2
Date of First Enrollment (India)	02/05/2017
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**1 **Months=**0 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Completed
Publication Details	None yet
Brief Summary	Insomnia is the most common sleep-related complaint with a prevalence of 6-18% in the general population. In South India, 18.6% of respondents reported insomnia. Chronic insomnia, if untreated, can have social, economic and occupational impacts on the individual. Insomnia is associated with impaired day-time functioning, reduced Quality of Life, increased risk of morbidity and substantial societal cost. There are multiple placebo controlled trials with results supporting the efficacy of homoeopathic medication in insomnia; still, one systematic review recommended that future trials of homeopathy and insomnia be conducted using adequate and rigorous study designs. In this trial, the investigators intend to assess the efficacy of individualized homoeopathic treatment for insomnia on 60 patients in a double blind, randomized, parallel arm, placebo controlled design in the outpatients of National Institute of Homoeopathy, Salt Lake, Kolkata 700106, West Bengal, India. The patients will be prescribed either individualized homoeopathic medicines or identical placebo, and will be followed up for 3 months. Data will be gathered at baseline and after 3 months using sleep diary and insomnia severity index questionnaire. Randomization will be pharmacy-controlled. Code will be broken at the end of the trial after the database is frozen. The Intention to treat (ITT) population will be subjected to statistical analysis.