

FULL DETAILS (Read-only) -> [Click Here to Create PDF for Current Dataset of Trial](#)

CTRI No	CTRI/2018/01/011166 [Registered on: 05/01/2018] Trial Registered Prospectively			
Acknowledgement Number	REF/2018/01/016705			
Last Modified On:				
Post Graduate Thesis	Yes			
Type of Trial	Interventional			
Type of Study	Drug Ayurveda Other (Specify) [Leech Application and Agni Karma]			
Study Design	Randomized, Parallel Group Trial			
Public Title of Study	Ayurvedic Management of Joint Pains			
Scientific Title of Study	A CLINICAL STUDY ON AGNIKARMA AND JALAUKA AVACHARANA WITH ABHA GUGGULU IN MANAGEMENT OF SANDHIGATA VATA (OSTEOARTHRITIS OF KNEE JOINT)			
Trial Acronym				
Secondary IDs if Any	Secondary ID	Identifier		
	NIL	NIL		
Details of Principal Investigator or overall Trial Coordinator (multi-center study)	Name	Dr Vyasadeva Mahanta		
	Designation	Associate Professor		
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Details Contact Person Scientific Query	Name	Dr Sanjay Kumar Gupta		
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Details Contact Person Public Query	Name	Dr Saroj Meena		
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Source of Monetary or Material Support	All India Institute of Ayurveda, Gautampuri, Sarita Vihar			
Primary Sponsor	Name	All India Institute of Ayurveda		
	Address	Gautampuri, Sarita Vihar, New Delhi - 110076		
	Type of Sponsor	Research institution and hospital		
Details of Secondary Sponsor	Name	Address		
	NIL	NIL		
Countries of Recruitment	India			
Sites of Study	No of Sites = 1			
	Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
	Dr Vyasadeva Mahanta	All India Institute of Ayurveda	OPD No 104, First Floor, Hospital Block, Dept of Shalya Tantra, All India Institute of Ayurveda, Gautampuri, Sarita Vihar	8368104072

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No of Ethics Committees= 1					
Details of Ethics Committee	Name of Committee	Approval Status	Date of Approval	Approval Document	Is IEC?
	Institutional Ethics Committee	Approved	12/08/2017	Approval File	No
Regulatory Clearance Status from DCGI	Status	Date	Approval Document		
	Not Applicable	No Date Specified	No File Uploaded		
Health Condition / Problems Studied Clarification(s) with Reply	Health Type		Condition		
	Patients		joint pain,		
Intervention / Comparator Agent	Type	Name	Details		
	Intervention	Abha Guggulu and Agnikarma	1 gm of Abha Guggulu thrice a day with like warm water after food will be administered for 30 days. Besides, agnikarma with Pancha dhatu Shalaka will be done once in a week, maximum four sittings will be done.		
	Comparator Agent	Abha Guggulu and Jalaukavacharana	1 gm of Abha Guggulu thrice a day with like warm water after food will be administered for 30 days. Besides this; Jalauka avacharana with 04 Jalaukas in 1 sitting will be done once in a week, maximum four sittings will be done.		
Inclusion Criteria	Age From	40.00 Year(s)			
	Age To	65.00 Year(s)			
	Gender	Both			
	Details	Patients suffering from Sandhigata Vata (Osteoarthritis of knee joint).			
Exclusion Criteria	Details	Patients with Knee joint effusion, Known cases of secondary OA due to TB, Syphilis etc.; suffering with Diabetes mellitus, Severe anaemia, malignancy, bleeding disorders etc.			
Method of Generating Random Sequence	Computer generated randomization				
Method of Concealment	Not Applicable				
Blinding/Masking	Open Label				
Primary Outcome	Outcome	To evaluate the comparative clinical efficacy of Agnikarma and Jalauka Avacharana of Management of Sandhigata Vata			TimePoints
					30 days
Secondary Outcome	Outcome	Improvement in quality of life			TimePoints
					2 Months
Target Sample Size	Total Sample Size="60" Sample Size from India="60" Final Enrollment numbers achieved (Total)= "Applicable only for Completed/Terminated trials" Final Enrollment numbers achieved (India)="Applicable only for Completed/Terminated trials"				
Phase of Trial	Phase 2/ Phase 3				
Date of First Enrollment (India)	02/04/2018				
Date of Study Completion (India)	Applicable only for Completed/Terminated trials				
Date of First Enrollment (Global)	No Date Specified				
Date of Study Completion (Global)	Applicable only for Completed/Terminated trials				
Estimated Duration of Trial	Years="1" Months="6" Days="0"				
Recruitment Status of Trial (Global)	Not Applicable				
Recruitment Status of Trial (India)	Not Yet Recruiting				
Publication Details	The outcome will be disseminated among peer reviewed journals.				
Brief Summary	Osteoarthritis (OA) is predominantly a disease of the elderly but no age is exempted. It is caused by wear and tear of the joint. In OA, the top layer of cartilage breaks down and wears away. Worldwide OA is the most common joint disorder. OA is the commonest form of joint disease which is a painful and disabling in advancing years of life. Before 60 years of age 10 out of 100 and after 60 years 75 out of 100 persons suffers from OA of				

knee joints. After 60 years of age, this disease creates so much trouble that medical consultation becomes mandatory. Worldwide OA is the most common articular disease of people of 65 years and above.

In Ayurveda OA can be correlated with *Sandhigata Vata*. It is characterised by the symptoms of *Shotha* (swelling), *Shula* (pain), *Vata Purna Driti Sparsha* (palpable as an air filled bag) and *Akunchana Prasarane Vedana* (pain on flexion and extension of the joint), *Hantisandhi* (structural changes) and *Atopa* (crepitus).

In modern medicine various treatment options are available like conservative treatment, epidural steroid injection, radicular infiltration, surgical methods but all modalities have their own limitations and certain complications. In Ayurveda, *Snehana*, *Upanaha*, *Agnikarma*, *Raktamokshana*, *Panchakarma*, *Bheshaja Chikitsa* etc. have been recommended in the management of such manifestations. Among these *Agnikarma* and *Raktamokshana* have their own therapeutic values in the management of *Sandhigata Vata*. *Jalauka avacharana* is a kind of *Raktamokshana*, which has gained greater attention globally because of its medical values. It is also a procedure advised in the management of OA.

Abha Guggulu is known for its *Shothahara* (anti-inflammatory), *Shulahara* (analgesic), *Rasyana* (Rejuvenative), *Sandhankara* (healing properties) actions. It is anticipated to be helpful in the treatment of OA. Though, it is being used in Ayurveda; but no comparative efficacy is available; considering which the current study is planned.