

Clinical trial on D.I.P Diet

Conducted by

All India Institute of Ayurveda

(Under Ministry of AYUSH)

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CTRI Number	CTRI/2018/12/016654 [Registered on: 13/12/2018] Trial Registered Prospectively	
Last Modified On:	12/12/2018	
Post Graduate Thesis	Yes	
Type of Trial	Interventional	
Type of Study	Medical Device Ayurveda	
Study Design	Other	
Public Title of Study	Role of agnikarma and diet in lower back pain	
Scientific Title of Study	A CLINICAL STUDY ON AGNIKARMA AND DIP(DISCIPLINED AND INTELLIGENT PERSON)DIET IN THE MANAGEMENT OF KATIGATASANDHI VATA WITH SPECIAL REFERENCE TO LUMBAR SPONDYLOSIS.	
Trial Acronym		
Secondary IDs if Any	Secondary ID	Identifier
	NIL	NIL
Details of Principal Investigator or overall Trial Coordinator (multi-center study)	Name	DR S K GUPTA
	Designation	H.O.D Dept. OF SHALYA TANTRA
	Affiliation	All india institute of ayurveda,mathura road,gautampuri,sarita vihar,new delhi-76
	Address	Department of shalya Tantra 5th floor academic block,All india institute of ayurveda,sarita vihar, gautampuri, new delhi South DELHI 110076 India
	Phone	8368403099
	Fax	
	Email	drskgupta17@gmail.com
Details of Contact Person Scientific Query	Name	DR S K GUPTA
	Designation	H.O.D Dept. OF SHALYA TANTRA
	Affiliation	All india institute of ayurveda,mathura road,gautampuri,sarita vihar,new delhi-76
	Address	Department of shalya Tantra 5th floor academic block,All india institute of ayurveda,sarita vihar, gautampuri, new delhi South West DELHI 110076 India
	Phone	8368403099
	Fax	

	Email	drskgupta17@gmail.com		
Details of Contact Person Public Query	Name	DrMONIKA SODE		
	Designation	PG Scholar 1st year		
	Affiliation	All india institute of ayurveda,mathura road,gautampuri,sarita vihar,new delhi-76		
	Address	Department of shalya Tantra 5th floor academic block,All india institute of ayurveda,sarita vihar, gautampuri, new delhi South DELHI 110076 India		
	Phone	9540596304		
	Fax			
	Email	monikasode0@gmail.com		
Source of Monetary or Material Support	All India Institute of Ayurveda, New Delhi			
Primary Sponsor	Name	all india institute of ayurveda		
	Address	All India Institute of Ayurveda, Matura Road,Gautam puri,Sarita Vihar		
	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 Monika Sode	All India Institute of Ayurveda	OPD No 6, Ground Floor, Hospital Block, South West DELHI	9540596304 monikasode0@gmail.com
Details of Ethics Committee	No of Ethics Committees= 1			
	Name of Committee		Approval Status	
	IEC		Approved	

Regulatory Clearance Status from DCGI	Status Not Applicable		
Health Condition / Problems Studied	Health Type Patients	Condition (1) ICD-10 Condition: M478 Other spondylosis,	
Intervention / Comparator Agent	Type	Name	Details
	Comparator Agent	Agni Karma	Four sessions of Agnikarma with Bindu dahan vishesha by pancha dhatushalaka at the interval of 7 days.
	Intervention	Agni Karma with DIP Diet	Four sessions of Agnikarma with Bindu dahan vishesha by pancha dhatushalaka at the interval of 7 days. This will be associated with DIP DIET - Daily for 1 month
Inclusion Criteria	Age From	20.00 Year(s)	
	Age To	60.00 Year(s)	
	Gender	Both	
	Details	Patients irrespective to their sex, religion, education and socio-economic status with cardinal features of Lumbar Spondylosis.	
ExclusionCriteria	Details	Patients of DM, TB of spine, fracture of spine, HIV, HBsAG, VDRL, osteopenia / osteoporosis or fracture of lumbar spine, Spondylolisthesis, ankylosing spondylosis, rheumatoid arthritis, Malignancy of lumbar vertebra	
Method of Generating Random Sequence	Computer generated randomization		
Method of Concealment	An Open list of random numbers		
Blinding/Masking	Open Label		
Primary Outcome	Outcome	TimePoints	
	Relief in cardinal symptoms of lumbar spondylosis.	One Month	
Secondary Outcome	Outcome	TimePoints	
	Improvement in quality of life by WHO QOL Scale.	18 months	
Target Sample Size	Total Sample Size="90" Sample Size from India="90" 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)	20/12/2018
Date of Study Completion (India)	Applicable only for Completed/Terminated trials
Date of First Enrollment (Global)	Date Missing
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 thesis work will be publish in reputed journal
Individual Participant Data (IPD) Sharing Statement	Will individual participant data (IPD) be shared publicly (including data dictionaries)?
Brief Summary	<p>Sandhigata Vata is a clinical condition develops when vitiated Vayuis localized at Kati Pradesha. The symptoms like Shoola, Shopha, Stambha etc. are developed. During the process of pathogenesis, Kapha Avrit Vyan Vayu obstruct the circulation of Rasa Rakta Dhatu and gradually structural changes are developed in Kati Pardesha. Acharya Charak has described this disease first time as 'Sandhigata Anila' under the chapter of Vatavyadhi (ch.ch.28/36). It is characterized by the features of Shoola (pain), Shotha (swelling) and Akunchana Prasarane Vedana (pain on flexion and extension of the joint), Hantisandhin (structural changes). Madhava has given one extra feature i.e. Aatopa (crepitus). Based upon its feature, Sandhigata Vata can be equated with Lumbar Spondylosis. Lumbar Spondylosis is a degenerative condition which affects the lower spine. In a patient with Lumbar Spondylosis, the spine is compromised by a narrowing of the space between the vertebrae, causing a variety of health problems ranging from back pain to neurological issues. WHO estimates that about 80% of individuals older than 40 years have lumbar spondylosis, increasing from 3% of individuals aged 20-29 years. Internationally, lumbar spondylosis can be developed in persons as young as 20 years. It increases with, and perhaps is an inevitable concomitant of age. In modern medicine various treatment options are available like conservative treatment, surgical methods but all modalities have their own limitation and complications. In Ayurveda Snehana, Upanaha, Agnikarma, Raktamokshana, Katibasti, Virechana, Bhesaja Chikitsa etc. have been recommended for management of Vatik disorders. Among these Agnikarma is a well-known para-surgical procedure and has its own therapeutic value for treatment of Sandhigata Vata (Lumbar spondylosis). Acharya Sushruta has mentioned Agnikarma procedure as a best among all other procedure (su.su 12/3) and in this study Pancha Dhatu Shalaka has been</p>

selected for Agnikarma. It is suitable for heat transfer and to produce Samyak Dagdha Vrana (ideal therapeutic burn). पथ्येऽसतिगदितास्यतिमौषधतिषेवर्तः ॥ पथ्येऽसतिगदितास्यतिमौषधतिषेवर्तः ॥ (लौतलम्बराज) That means those people have no use to give medicine who did not follow proper diet. And for those who actually follow proper diet there is no need of medicine for them. Ahara (food), Nidra (sleep) and Brahmacharya (celibacy) are the Traya Upastambhas (Trayopastambhas) explained in Ayurveda. Among the three pillars, Ahara or food is a major supporting pillar which helps in sustenance of life and maintenance of health. One cannot imagine living without food. Acharya Charaka Samhita gives a beautiful concept about Ahara and tells that the Ahara not only forms this body but also forms the diseases which occur in us. If the wholesome food (Hita Ahara) is responsible for Sukha (happiness, health), the unwholesome food (Ahitahara) causes Dukha (misery, unhealthy). He also tells that Ahara or food is the best among the things which sustain the life. (ch.su.28/45) Kashyapa tells that no medicine is equivalent to the Ahara or food. He also calls Ahara as Maha Bhaishajya (greatest and best medicine). Just by the administration of proper food and diet it is possible to cure the diseases even without the need of administration of medicines and treatment. (ka.sm.khl.4/5) Any disease can be comprehensively cured without any medicine by just following 'pathya Ahara' or wholesome food whereas even hundreds of medicines and formulations cannot cure a disease in the absence of a planned wholesome regimen of diet.

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