## **CLINICAL RESEARCH**

## 2017-18

- No. of ongoing studies 10
- No. of concluded studies- 13
- No. of new studies initiated-7
- Publication 9
  - 1. Homoeopathic research in vitiligo: Current scenario Indian Journal of Research in Homoeopathy; 2017; 11(4):226-236
  - 2. A retrospective study of homoeopathic treatment in patients with heel pain with or without Calcaneal Spur Indian Journal of Research in Homoeopathy; 2017:11(1):64-73
  - 3. Homoeopathic treatment of ulcerative Colitis: A case report Indian Journal of Research in Homoeopathy; 2017:11(1):74-78
  - 4. A case report of fibroadenosis alleviated with Homoeopathy Indian Journal of Research in Homoeopathy;2017:11(3):196-202
  - 5. A case of radiation-induced mucositis Indian Journal of Research in Homoeopathy; 2017:11(4):257-61
  - 6. Model validity of randomised placebo-controlled trials of non-individualised homeopathic treatment. Homeopathy; 2017;106 (4):194-202
  - 7. Acute encephalitis syndrome/Je: homoeopathic perspective. Healthy India Chronicle 2017; 1(1): 76-79.
  - 8. Evaluation of homoeopathic treatment in polycystic ovary syndrome: A single-blind, randomised, placebo-controlled pilot study. Indian Journal of Research in Homoeopathy 2018; 12: 35-45.
  - 9. A Case Report Of Ureteric Calculus Treated With Homoeoapthic Medicine Hydrangea Arborescens 30. Indo American Journal Of Pharmaceutical Sciences; 2018:5(1):627-633

S.No.	Name of the project	Period of study	Status	Outcome	Publication		
Concluded studies:							
1.	Effects of individualized homoeopathic intervention in Dyslipidemia: an open label randomized controlled exploratory trial.	October 2013 to March 2018	Concluded	Since its inception in October 2013, a total of 3070 patients have been screened and 217 are enrolled. During the reporting period, 209 were screened and 17 have been enrolled. The study has been concluded in March 2018 and the data is under the process acquisition, cleaning and analysis.	Data analysis under process		
2.	Effects of homoeopathic intervention in Stage I Essential Hypertensive Patients: A randomized double blind, placebo controlled trial.	October 2013 to March 2018	Concluded	Since inception in October 2013, 1981 patients have been screened and 214 are enrolled. During the reporting period, 129 were screened and 23 have been enrolled. The study has been concluded in March 2018 and the data is under the process acquisition, cleaning and analysis.	Data analysis under process		
3.	Effects of homoeopathic intervention in Pre-Diabetes (EHIP): an open label randomized controlled exploratory trial.	October 2013 to March 2018	Concluded	Since inception in November 2013, 4083 patients have been screened and 401 are enrolled. During the reporting period, 418 were screened and 27 have been enrolled. The study has been concluded in March 2018 and the data is under the process acquisition, cleaning and analysis.	Data analysis under process		
4.	Homoeopathy as adjunctive treatment to Resperidone/Olanzapine in treatment resistant patients of Schizophrenia: an open label randomized placebo controlled trial	30th May 2017.	Concluded	Since inception, 805 cases were screened, 184 enrolled. During the reporting period, follow up of enrolled patients continued. The study has been concluded in September 2017 and the data is under the process acquisition, cleaning and analysis.	Data analysis under process		
5.	A randomized placebo controlled, cross-over, clinical trial of homoeopathic medicine	June 2012 to September 2017	Concluded	Since inception, 535 patients have been screened and 81 are enrolled. During the reporting period, follow up of enrolled patients continued. The study has been concluded in September 2017 and	Data analysis under process		

S.No.	Name of the project	Period of study	Status	Outcome	Publication
	in Autism.			the data is under the process acquisition, cleaning and analysis.	
6.	Effectiveness of homeopathic medicines- as add on to institutional management protocol for Acute Encephalitis Syndrome (AES) – A case control study.	July 2016 to March 2018	Concluded	An equivalent 339 cases of AES cases are being captured from the hospital records as control for comparison of the outcome retrospectively. The study is concluded. The data capturing is under process.	Data analysis under process
7.	Efficacy of homoeopathic medicine Belladonna 200 in preventing Acute Encephalitis Syndrome in children residing in an endemic region - A cluster randomized, double blind, double arm, placebo controlled trial	July 2013 to December 2015	Concluded	A total of 44679 children were distributed belladonna 200/ placebo to assess the preventive role of belladonna 200 in acute encephalitis of children. The data entry is under process and will be analyzed.	Data analysis under process
8.	Individualized Homoeopathic intervention in Diabetic Foot Ulcer: a randomized controlled pilot study using Calendula Q vs normal saline for ulcer dressing.	May 2014 to November 2017	Concluded	Since inception, 277 patients were screened, 60 enrolled and 57 cases completed the follow up. During reporting period, 32 patients were screened and 17 patients enrolled.  29 cases improved in Homoeopathy + Calendula and 28 cases in Homoeopathy + Normal saline.  Both the groups showed equal improvement with respect to complete closure and epithelialization of the ulcer.	Data analysis under process
9.	Observational study to evaluate response to homoeopathic treatment in vitiligo	December 2014 to March 2018	Concluded	Since inception of the study 1171 cases have been screened and 481 cases have been enrolled. During the reporting year, 246 cases have been screened and 56 cases have been enrolled. Study	Data analysis under process

S.No.	Name of the project	Period of study	Status	Outcome	Publication		
				has been concluded and data verification and analysis of cases is in process.			
10.	Observational study to evaluate response to homoeopathic treatment in psoriasis	September 2014 to March 2018	Concluded	Since inception of the study 1711 cases have been screened and 519 cases have been enrolled. During the reporting year, 294 cases have been screened, 116 cases have been enrolled. Study has been concluded and data verification and analysis of cases is in process.	under process		
11.	Comparing individualized homoeopathy with placebo in managing pain of knee osteoarthritis: a double- blind randomized controlled trial.	October 2015 to March 2018	Concluded	Since inception 1097 cases have been screened and 351 cases have been enrolled. In the reporting year, 217 patients have been screened, 85 patients have been enrolled. Study has been concluded and data verification and analysis of cases is in process.	Data analysis under process		
12.	Homoeopathic Ferrum drugs in treatment of Iron deficiency anemia in children.	September 2015 to March 2018	Concluded	Since inception in Phase I 3080 cases have been screened and in Phase II 730 cases have been screened out of which 100 cases have been enrolled. Study has been concluded and data verification and analysis of cases is in process.	,		
13.	Follow up cross sectional study of Subclinical Hypothyroidism children post five years of treatment	June 2015 to March 2018	Concluded	The secondary objectives were to compare the health status of children between intervention with placebo group post 5 years of treatment and to compare the overt rate in children between intervention with placebo post 5 years of treatment. The outcome measures were FT3, FT4, TSH and Anti-TPO antibodies.	Data analysis under process		
Ongoi	Ongoing studies						
1.	A Comparative Randomized Controlled Trial of Homoeopathy & Allopathy in Acute Otitis Media & its recurrence in Children.	October 2014 to November 2018	Ongoing	Since inception in November 2014, a total of 396 cases were screened and 235 were enrolled. During the reporting period, 44 and 26 cases were screened and enrolled respectively. Further enrollment of patients in the study has been	Ongoing		

S.No.	Name of the project	Period of study	Status	Outcome	Publication
2.	A multi-centric single blind randomized placebo controlled trial to evaluate the efficacy of individualized homeopathic intervention in Breast Fibroadenoma.	to June 2018	Ongoing	stopped. The enrolled patients are under follow up. Since inception, 594 patients were screened and 171 enrolled. During reporting period, 102 were screened & 24 patients enrolled. The enrolment has been stopped in December 2017. Since then, the enrolled patients are under follow up.	Ongoing
3.		December 2016 to march 2018	Ongoing	Since inception in 2016, 1288 patients have been screened and 482 cases have been enrolled. During the reporting year, 912 cases have been screened and 338 cases have been enrolled. Arsenic album, Causticum, Bryonia and Belladonna are among the most prescribed medicines in the study. Feedback from the investigators on pre-trial phase has been gathered and based on this, and on other challenges in the pre-trial phase, the protocol is being modified for trial phase of the study, which will be initiated soon.	Ongoing
4.	Management of Chronic Non Specific Low Back Pain (NSLBP) with homoeopathic intervention versus placebo along with directional preference exercise -A parallel arm randomized controlled pilot study.	- till date	Ongoing	Since inception of study out of 262 screened cases, 76 enrolled, 4 drop out, 51 cases are under follow up and 21 cases completed the study with follow up of 3 months as per protocol. Till date Lycopodium, Pulsatilla, Sulphur, Rhus tox. & Causticum found to be effective.	Ongoing
5.	,	Oct. 2015 till date	Ongoing	Since inception of the study, 207 cases have been screened, 162 cases were enrolled, and 65 cases have completed follow-up as per the protocol. During the reporting year, 101 cases were screened, 83 cases were enrolled; and 25 cases have completed follow-up as per the protocol. The	Ongoing

S.No.	Name of the project	Period of study	Status	Outcome	Publication
				medicines found effective so far are Sulphur, Natrum-mur, Calcarea-carb, Pulsatilla	
6.	Validation of commonly used homoeopathic drugs for bronchial asthma: A prospective observational study	Oct. 2015 till date	Ongoing	Since inception of the study, 436 cases have been screened, 85 cases were enrolled, and 25 cases have completed follow-up as per the protocol. During the reporting year, 132 cases were screened, 33 cases were enrolled; and 3 cases have completed follow-up as per the protocol. The medicines found effective so far are <i>Arsenic-alb</i> , <i>Phosphorus</i> , <i>Natrum-mur</i> , <i>Pulsatilla</i> .	Ongoing
7.	Validation of commonly used homoeopathic drugs for functional dyspepsia: A prospective observational study	Oct. 2015 till date	Ongoing	Since inception of the study, 869 cases have been screened, 454 cases were enrolled, and 251 cases have completed follow-up as per the protocol. During the reporting year, 349 cases were screened, 154 cases were enrolled; and 72 cases have completed follow-up as per the protocol. The medicines found effective so far are <i>Nux-vom</i> , <i>Carbo-veg</i> , <i>Lycopodium</i> , <i>China and Sulphur</i> .	Ongoing
8.	Validation of commonly used homoeopathic drugs for haemorrhoids: A prospective observational study	Oct. 2015 till date	Ongoing	Since inception of the study, 573 cases have been screened, 194 cases were enrolled, and 90 cases have completed follow-up as per the protocol. During the reporting year, total 253 cases were screened out of which 73 cases have been enrolled; and 27 cases have completed follow-up as per the protocol. The medicines found effective so far are <i>Sulphur</i> , <i>Nux-vomica</i> , <i>Phosphorus and Arsenic-album</i> .	Ongoing
9.	Validation of commonly used homoeopathic drugs for migraine: A prospective observational study	Oct. 2015 till date	Ongoing	Since inception of the study, 214 cases have been screened, 69 cases were enrolled, and 20 cases have completed follow-up as per the protocol. During the reporting year, total 97 cases were screened out of which 41 cases have been enrolled; and 13 cases have completed follow-up as per the protocol. The medicines found effective	Ongoing

S.No.	Name of the project	Period of study	Status	Outcome	Publication
				so far are <i>Natrum-mur</i> , <i>Calcarea-carb</i> , <i>Belladona</i> , <i>Phosphorus and Nux-vomica</i> .	
10.	Efficacy of Homoeopathic treatment in Sub- Clinical Hypothyroidism in school going children: A randomized double blind placebo controlled parallel arm trial	June 2015 to June 2020	Ongoing	Since inception of the study, 2084 children have been screened, 109 children were enrolled.	Ongoing
New s	studies initiated				
1.	Homoeopathic management of symptomatic adenotonsillar hypertrophy in children: A Prospective observational study.	September 2017 to March 2020	ongoing	Since inception in September 2017, 137 patients have been screened and 79 are enrolled. 4 patients have completed follow up since inception	ongoing
2.	Evaluation of Homoeopathic treatment in the Out Patient Department - A patient reported outcome study	August 2017 till date	ongoing	Homoeopathic general questionnaire for assessing the prevalence of general symptoms in homoeopathy has been filled in 8072 population, Measure Your Outcome Profile (MYMOP) has been filled in 7008 OPD patients. The data capturing is under process.	ongoing
3.	A Multicentric randomized, double blind, placebo controlled study to evaluate efficacy of predefined homoeopathic medicines in treatment	2017, till date	ongoing	Since inception 94 cases have been enrolled and are under follow up	ongoing

S.No.		Period of study	Status	Outcome	Publication
4.	of Warts.  Usefulness of individualized Homoeopathy versus standard allopathic treatment in acute uncomplicated Urinary Tract Infection (UTI): A randomized comparative trial	December 2017- December 2020	ongoing	In pre-trial phase, 09 cases screened out of which 05cases have been enrolled at Kottayam and Kottayam centre, under homoeopathic arm only	ongoing
5.	Management of Rheumatoid Arthritis with individualized Homoeopathy- An observational study"	December 2017- December 2020	ongoing	The target sample size is 160 cases (40 patients /centre) and it will be implemented at 4 centres :DDPRCRI (H), Noida; NHRIMH, Kottayam; RRI(H), Gudivada and Mumbai.	ongoing
6.	Management of post chikungunya arthritis with Homoeopathy Vs Standard conventional treatment- A comparative open randomized control trial	February 2018- February 2021	ongoing	A total of 90 cases will be enrolled with 30 cases/per centre at its 3 centres (DDPRCRI (H), Noida; NHRIMH, Kottayam; RRI(H), Gudivada) once the outbreak of Chikungunya	ongoing
7.	Effect of Homoeopathic medicines in the management of morbidity associated with grade III and grade IV lower limb lymphoedema due to lymphatic filariasis – A prospective clinical trial	March 2018- March 2021	ongoing	The project has recently initiated. Pre trial preparation in process.	ongoing