CLINICAL RESEARCH- ONGOING STUDIES- 2022

Sl.No.	Title of the study	Study design	Study site	Outcome(s)
1.	Management of Rheumatoid Arthritis with individualized Homoeopathy- An observational study	Observational Study	• Dr. D.P. Rastogi Central Research Institute for Homoeopathy, UTTAR PRADESH • National Homoeopathy Research Institute in Mental Health, KERALA • Regional Research Institute(H), ANDHRA PRADESH • Regional Research Institute(H), Mumbai, MAHARASHTRA	**Primary outcome** • To assess and compare the changes in the DAS 28 CRP score from baseline, at 3rd, 6th, 9th and 12th month in Clinical improvement of Rheumatoid Arthritis **Secondary outcome** • To assess and compare the changes in activity profile and quality of life of Rheumatoid Arthritis patients using ACR 20 response criteria
2.	Usefulness of individualized Homoeopathy versus standard allopathic treatment in acute uncomplicated Urinary Tract Infection (UTI): A randomized comparative trial	Randomized comparative trial	• Dr Anjali Chatterjee Regional Research Institute for Homoeopathy, WEST BENGAL • Dr DP Rastogi Central Research Institute for Homoeopathy, UTTAR PRADESH • National Homoeopathic Research Institute in Mental Health, KERALA	**Primary outcome** • To assess and compare clinical outcome of treatment with homoeopathic medicine and allopathic medicine in uncomplicated UTI [symptom severity and duration using UTI Symptoms Assessment questionnaire (UTISA)] **Secondary Outcome** • To compare the changes in quality of life in response to both treatment groups. • To compare the changes in urine culture after homoeopathic Vs. allopathic treatment (micro biological outcome). • To assess any recurrence of sign/symptoms of UTI for 6 months follow-up.
3.	An open exploratory clinical trial to assess the efficacy of homoeopathic medicines in the	Observational Study	Regional Research Institute for Homoeopathy, Puri	**Primary outcome** • To assess and compare the clinical improvement in grade III and grade IV unilateral/bilateral lower limb lymphedema at the end of 01 year by a. Determining the changes in limb circumference using tape measure following the protocol

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	management of morbidity associated with grade III and grade IV lower limb lymphoedema in patients with lymphatic filariasis			described by the Australasian Lymphology Association (ALA). b. Volume changes in lymphoedema by 'Water Displacement Method'. **Secondary outcome** • To assess and compare QOL using 7D5L scale To assess and compare Og4C3 and TNF-alfa. • To assess and compare Dermatology Life Quality Index (DLQI). • To assess and compare ADL attacks at the end of one year treatment. • To assess and compare the changes in joint mobility. • To assess and compare skin health.
4.	Management of Adjustment Disorders with homoeopathic intervention: A prospective, single-arm, open-label, exploratory, interventional study	Observational Study	• Anjali Chatterjee Regional Research Institute for Homeopathy, WEST BENGAL • Clinical Research Unit (T), WEST BENGAL • Clinical Research Unit (T), SIKKIM • Clinical Research Unit (T), JHARKHAND • Clinical Verification Unit (H), BIHAR • National Homoeopathy Research Institute in Mental Health (NHRIMH), KERALA • Regional Research Institute (H), ORISSA	**Primary outcome** • To compare the changes in severity of adjustment disorders at baseline and fortnightly for 3 months using PHQ-4. **Secondary Outcome** • To compare the changes in severity of adjustment disorders at baseline, 1st, 2nd and 3rd month using PSS.
5.	Effectiveness Of Homoeopathy in Children	Observational Study	Homoeopathy Research Institute for Disabilities, TAMIL NADU	**Primary Outcome** • Change in IQ test score assessed by Binet Kamath test of Intelligence.

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	with Intellectual Disability			• Change in Behavioural Assessment Scales for Indian Children with Mental Retardation (Part –A and B) (BASIC MR) Change in Vineland Social Maturity Scale (VSMS) **Secondary outcome** • Response to medicine prescribed based on symptomatology and clinical presentation. • Response of co-morbidities in children based on symptoms and examination findings.
6.	Management of Trigeminal Neuralgia with Homoeopathic Intervention as an add-on to the Standard treatment – A double blind, randomised controlled trial	Randomized Controlled Trial	Janakpuri Super Speciality Hospital, DELHI	**Primary outcome** • change in BPI-Facial Score. **Secondary Outcome** • Change in total and individual domain scores in BPI-Facial
7.	A Multicentric randomized, double blind, placebo-controlled study to evaluate efficacy of predefined homoeopathic medicines in treatment of Warts.	Randomized Controlled Trial	• Dr. Anjali Chatterjee Regional Research Institute for Homoeopathy, Kolkata, WEST BENGAL • Dr. D. P. Rastogi Central Research Institute of Homoeopathy, Noida, UTTAR PRADESH • Princess Durru Shevar Hospital, Ext. center of Drug Standardization Unit, Hyderabad, ANDHRA PRADESH	**Primary outcome** • Determine the percentage of warts disappeared. **Secondary outcome** • To validate the symptoms of the pre-defined 09 drugs in warts.

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			• Regional Research for Homoeopathy, Agartala, TRIPURA • Regional Research Institute for Homoeopathy, Gudivada, ANDHRA PRADESH • Regional Research Institute Homoeopathy, Jaipur, RAJASTHAN • Regional Research Institute Homoeopathy, Navi Mumbai, MAHARASHTRA • Regional Research Institute Homoeopathy, Puri, ORISSA	
8.	Management of polycystic ovarian syndrome with homoeopathic intervention versus standard conventional treatment -A non-randomised comparative study	Non-randomised comparative study	• Dr. D.P. Rastogi Central Research Institute for Homoeopathy, UTTAR PRADESH • Drug Standardization Unit, Hyderabad, TELANGANA	**Primary outcome** • Establishment of regular menstrual cycle along with either ultrasonological improvement of PCO or improvement in acne. **Secondary outcome** • To compare the pregnancies achieved in cases of infertility in homoeopathy and conventional intervention groups. • To compare the changes in domain scores of PCOSQ in both homoeopathic group and conventional treatment group at monthly intervals for 6 months. • To compare the changes in ultrasound reports of PCO at entry and 6 months in homoeopathy and conventional groups. • To compare the changes in insulin resistance through HOMA-IR in two groups
9.	An open Label, interventional,	Observational Study	Delhi Cantonment General Hospital, DELHI	**Primary outcome** • change in severity of OLP.

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	prospective, pilot Study to Evaluate Response to Individualized homoeopathic treatment in case of oral lichen planus			• Metric/method of measurement: VAS for pain intensity and Escudier Disease Severity Score. • Participant level Analysis Metric: The outcome value at one year from the baseline will be used for statistical analysis. • Time point of primary interest: The scale measurement will be taken at baseline and at every follow up. The subject if be lost to follow up then the last available value will be considered. **Secondary Outcome** • The secondary outcome measure is general outcome of the patient after treatment and change in oral health related QoL of the patient. • Metric/method of measurement: OHIP- 14, relevant laboratory investigations, progress of the case as per signs and symptoms, ORIDL score by the investigator and MYMOP2 score by the patient. • Time point of primary interest: Relevant investigations will be done at the baseline and at the end of treatment or as when required.
10.	Effectiveness of Homoeopathy with standard care vs Standard care alone in patients with chronic kidney disease on haemodialysis: an open label, pragmatic randomized, controlled,	Randomized Controlled Trial	Agartala Government Medical College Kunj ban, Agartala, Tripura	**Primary outcome** • To compare the changes in quality of life using KDQOL 36 at different months till 6 months in both the group. **Secondary outcome** • To determine the changes in Kidney function tests at different time points. • To determine the Change in eGFR at different time points till 6 months • No. of dialysis after initiation of treatments in both the groups

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	feasibility trial (A pilot study)			
11.	A Multicentric, Open label, Prospective, Observational Study to evaluate effect of Individualised Homoeopathic Medicines in Tinea Corporis and Tinea Cruris	Observational Study	• Central Research Institute for Homoeopathy, RAJASTHAN • Clinical Research Institute for Homoeopathy, ANDAMAN & NICOBAR ISLANDS • Clinical Research Unit of Homoeopathy, JHARKHAND • Dr. D.P. Rastogi Central Research Institute of Homoeopathy Noida, UTTAR PRADESH • Regional Research Institute of Homoeopathy, ANDHRA PRADESH • Regional Research Institute of Homoeopathy Puri, ORISSA	**Primary Outcome** • Clinical and Mycological assessment of Tinea lesion at baseline, and end of Treatment. • Clinical cure (resolution of sign and symptoms) Mycological assessment is based on KOH mounting for dermatophytes. **Secondary outcome** • Global Evaluation Response by the physician. • Evaluation of effect on Quality of life of Tinea patients using SKINDEX 16
12.	Homoeopathic treatment of respiratory sequelae of post-covid cases: an open-label prospective study (in collaboration with AIIMS New Delhi)	Observational study	• AIIMS, New Delhi,	**Primary outcome** • To study the role of homoeopathic treatment in Respiratory sequelae of Post COVID cases. **Secondary outcome** • To study the time of recovery.
13.	Pragmatic study of Homoeopathy as adjuvant therapy given along with standard medical	Observational study	• Motiwala Homoeopathic Medical College, Nashik, MAHARASHTRA	**Primary outcome** • Annualized bleeding rate for all bleeds (ABRall) at the end of 01 year • Annualized bleeding rate for joint bleeds (ABRjoints) at the end of 01 year

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	management in Persons with Hemophilia and other bleeding disorders ((in collaboration with Motiwala Homoeopathic Medical College, Nashik, MAHARASHTRA)			**Secondary outcome** • Haemophilia Joint health score (HJHS) • Pediatric Haemophilia Activities List (PaedHAL)and Haemophilia Activities List (HAL) • Haemo QoL • Requirement of blood transfusion during study • Inhibitor titre