

Clinical Research

2012-13

No. of studies undertaken	No. of publication
9	4

The details of the studies undertaken year wise along with the outcomes is given below:

SNo	Name of Project	Period of Study	Status	Outcome	Publication
1.	Homoeopathic therapy for lower urinary tract symptoms in men with Benign Prostatic Hyperplasia: A randomized multicentric clinical trial	July 2012 to January 2014	Concluded Manuscript under preparation	<p>Objectives: The primary objective is to compare the changes in International Prostate Symptom Score (IPSS) within the three groups in the study, namely Homoeopathic Constitutional (HC) remedy, Homoeopathic Constitutional + Organ remedy (HC + O) and Placebo (PL). The secondary objectives are to compare the changes in Prostate volume (PV), Post Void Residual Urine (PVRU), Uroflowmetry and in WHOQOL-BREF.</p> <p>Material and Methods: A multicentric three-armed randomized clinical trial was conducted at five centers under Central Council for Research in Homoeopathy. Patients were enrolled following the predefined inclusion and exclusion criteria, randomised in 2:2:1 ratio and were followed for six months. To evaluate the role of intervention, internationally validated scales were used. The analysis of these patients as per protocol and as per intention to treat was carried out using repeated measures ANOVA and paired t test.</p> <p>Results: Out of 461 screened cases, 254 patients were enrolled in the study (HC=103, HC + O = 102 and PL = 49), 152 were</p>	-

SNo	Name of Project	Period of Study	Status	Outcome	Publication
				<p>analyzed as per protocol and 241 cases were analyzed under ITT. Statistically significant result was noted in IPSS score at six months from baseline in all the three groups ($P < 0.05$). Statistical significance was also found in the secondary outcome measures WHO-QOL BREF and Q MAX in HC and HC+O group.</p> <p>Conclusion: HC and HC + O are found equally effective in symptomatic relief to the patients but for looking at the objective parameters, studies may be taken up with larger sample size.</p>	
2.	A randomized open controlled trial of predefined homoeopathic medicines on Acute Adenolymphangitis (ADL) due to Lymphatic Filariasis.	October 2012 to April 2014	Concluded Manuscript under preparation	<p>Background: Episodic adenolymphangitis (ADL) is an important clinical manifestation of lymphatic filariasis. Recurrent ADL's has a great socioeconomic implication as it causes a significant loss of man days and is the world's second leading cause of disability.</p> <p>Objective: <i>This study aimed at comparing the effectiveness of homoeopathic treatment with standard allopathic treatment of acute adenolymphangitis (ADL) using ADL scoring scale.</i></p> <p>Materials and methods: <i>Study was conducted from October 2012 to April 2014. A total of 112 patients (Homoeopathy-55 and Allopathy-57) were randomized to receive either homoeopathic treatment or standard allopathic treatment for a period of six months. Outcome measures were ADL scoring scale and quality of life scale (WHOQOL-BREF).</i></p> <p>Results: A total of 112 patients (homoeopathy- 55 and</p>	-

SNo	Name of Project	Period of Study	Status	Outcome	Publication
				<p>Allopathy- 57) were analyzed for intensity and duration of ADL attacks. When compared after six months, 9/11 cases in homoeopathic group showed recurrence of attack in mild intensity whereas in allopathic group, 14/16 recurred cases were of moderate intensity. When compared for duration of subsequent attacks, all 16 cases in allopathic group had attack for 1-3 days whereas in homoeopathic group only 10 patients had attack which lasted for 1-3 days. The quality of life of the patients were also improved after homoeopathic intervention as evident from the Quality of life questionnaire.</p> <p>Conclusion: The Randomized trial provides evidence to support the fact that individualized homoeopathic treatment is equally effective for ADL as the allopathic treatment.</p>	
3.	Adjuvant homoeopathic management for cancer patients experiencing side effects form chemotherapy- A pilot study.	August 2012 to June 2016	Concluded Under analysis	A total of 29 patients were screened and 28 patients were enrolled.	
4.	Lycopodium clavatum in Urolithiasis: A randomized, double blind, placebo controlled clinical trial.	June 2012 to March 2015	Concluded Manuscript under preparation	A total of 753 patients were screened and 134 patients were enrolled.	
5.	Comparative trial in the management of Alcohol dependence:	October 2012 to October 2014	Concluded	<p>Objectives: This study was undertaken to compare the effects of IH with standard allopathic (SA) treatment.</p> <p>Methods: A randomized</p>	Indian J Res Homoeopat

SNo	Name of Project	Period of Study	Status	Outcome	Publication
	standard allopathy treatment vs. homoeopathy – A randomized trial.			<p>controlled, open-label, comparative trial, was conducted, in which alcohol dependents were screened verbally using the CAGE scale. The participants 80 patients fulfilling the inclusion criteria were randomized either IH (n=40) or SA (n=40) and treated cum followed up for 12 months. The primary outcome was more than 50% reduction in the Severity of Alcohol Dependence Questionnaire [SADQ] rating scale at 12th month. Data analysis was done for both intention-to-treat (ITT) and per-protocol (PP) populations. Results: ITT analysis reflected 80% (n = 32) of the patients in IH and 37.5% (n = 15) of the patients in the SA responding to CI before 2.4 treatment with absolute difference was 42.5% (42.5 [95% confidence interval [CI]: 23.0, 61.6]) and estimated effect: 6.6 (95% C.I: 2.4, 18.2), P = 0.0002. A significant difference favoring IH was also observed in three out of four domains of WHO QOL-BREF. Statistically significant difference was found in the number of drinking days (median difference: -24.00; CI: -39.0--8.0; P = 0.001) and number of drinks per drinking day (median difference: -6.3 [95% CI: -11.3--1.9]; P = 0.004), favoring IH. The results showed a similar trend in PP analysis. Medicines found useful were <i>Sulphur</i>, <i>Lycopodium clavatum</i>, <i>Arsenicum album</i>, <i>Nux vomica</i>, <i>Phosphorus</i>, and <i>Lachesis</i>.</p> <p><i>Conclusion:</i> The results conclude that IH is not inferior to SA in the management of AD patients.</p>	hy 2016; 10:172-81

SNo	Name of Project	Period of Study	Status	Outcome	Publication
				More rigorous studies with large sample size are however desirable.	
6.	A randomized, placebo controlled, cross-over, clinical trial of homoeopathic medicines in Autism.	Nov. 2012 to till date	Ongoing	A total of 453 screened and 81 cases are enrolled	
7.	A randomized double blind placebo controlled multicentric trial on the effects of Homoeopathic medicines on Chronic Rhinosinusitis.	July 2012 to December 2013	Concluded Manuscript under preparation	A total of 317 screened and 121 cases are enrolled	-
8.	A single-blind, open, randomized, placebo-controlled trial of add-on homeopathic therapy in patients of severe Leptospirosis on conventional care.	Sept.. 2012 to Feb. 2014	Withdrawn	A total of 213 patients were screened and 160 were excluded. 53 patients were enrolled wherein individualized Homoeopathic medicine was being administered as an adjuvant to standard care (Homoeopathy + standard care: 26; Placebo + standard care: 27). All the patients in the trial were improved. There was no death reported. Due to difficulty in enrollment and target completion, the study is withdrawn in January 2015 after approval from in the meeting of 57th Scientific Advisory Committee of the Council.	
9.	Homoeopathy as adjunctive treatment to resperidone/olanzipine in treatment resistant	May 2013 to till date	Ongoing	A total of 780 patients are screened and 184 cases are enrolled	

SNo	Name of Project	Period of Study	Status	Outcome	Publication
	patients of Schizophrenia: An open label randomized placebo controlled trial.				

Publications under Clinical Research Program (2012-13):

1. Homeopathy in Chronic Sinusitis: A Prospective Multi-centric observational Study. Homeopathy, 2012; 101(2): 84–91.
2. A prospective observational study to ascertain the role of homeopathic therapy in the management of diabetic foot ulcer. Indian Journal of Research in Homoeopathy 2012; 6 (2): 22--31
3. Homoeopathic medicines in the management of benign prostatic hyperplasia: A multi-centric prospective observational study. Indian Journal of Research in Homoeopathy 2012; 6 (3) : 16-25
4. Homoeopathic individualized LM-potencies versus Centesimal potencies for pain management of cervical spondylosis: A multicenter prospective randomized exploratory clinical study.Indian Journal of Research in Homoeopathy, 2012; 6(4):16-23.