

Generation of evidence for safety of Ayurveda medicine: CCRAS initiatives

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Central Council for Research in Ayurvedic Sciences (CCRAS) is committed to promote research in important disease areas of national priority. Therefore, the Research Policy of CCRAS is aimed at encouraging its scientists for the formulation, submission and execution of research projects for generating quality data for scientific validation of safety and efficacy of formulations/therapies and other interventions including basic principles. CCRAS has laid policies for internal scientists, external scientists, for collaborative research in abroad as well as R&D policy for already marketed drugs.

Council has adopted, Intra Mural Research Scheme by which the regular scientific staff of CCRAS are at liberty to develop the project keeping in view the National Priority Areas and Strength areas of Ayurveda. CCRAS is also working in collaboration with many premier research institutions for integrative and safety studies of various Ayurveda interventions under a collaborative research scheme at National level and at international platform. Council has also laid policy for research with the industries for promoting research and commercializing the research product so it can be utilized by public at large.

Clinical Research and Drug development: The council is working towards validation of classical medicines. Council has done Pharmacological studies of about 400 Ayurvedic drugs/formulations and have generated scientific evidence on safety and efficacy of approximate 82 classical Ayurvedic formulations on 24 diseases/conditions viz. Allergic Conjunctivitis, Bronchial Asthma, Chronic Bronchitis, Cognitive Deficit, Dry Eye Syndrome, Dyslipidemia, Type II Diabetes Mellitus, Essential Hypertension, Irritable Bowel Syndrome (IBS), Iron Deficiency Anemia, Menopausal Syndrome, Osteoarthritis, Obesity, Osteoporosis/Osteopenia, Rheumatoid Arthritis, Rasayana for healthy ageing, Dysmenorrhea, Psoriasis, Gout, Polycystic Ovary Syndrome, Hemorrhoids, Mental Retardation, Generalized Anxiety Disorder and Computer Vision Syndrome. Further validation of approximate 32 classical Ayurvedic formulations is continuing for generation of scientific evidence

on safety and efficacy on 14 diseases/conditions viz. Psoriasis, Urolithiasis, Uterine Fibroids, Rheumatoid Arthritis, Hemorrhoids, Osteoarthritis, Gout, Osteopenia/Osteoporosis, Obesity, Iron Deficiency Anemia, Menopausal Syndrome, Cervical Spondylosis, Cognitive Deficit and Chronic Allergic Conjunctivitis. Council is also working towards development of new drug, taking leads from Ayurveda literature and from folklore claims collected from different parts of India.

Till date, 12 technologies have been developed and commercialized through National Research Development Corporation (NRDC) for wider public utility including drugs for disease.

Diabetes: CCRAS has successfully developed an Anti diabetic drug **Ayush 82**, developed after series of safety toxicity studies which have shown no toxic sign even at 10 times of intended therapeutic dose. The drug have shown statistically significant reduction in fasting and post prandial blood sugar level along with clinical improvement in diabetes mellitus without any adverse effect.

Malaria: CCRAS has developed an Anti malarial drug **Ayush-64** through extensive pharmacological, toxicological and clinical studies. It has been patented by council through National Research and Development Corporation, New Delhi (Patent No. 152863). The study was done in collaboration with National Malaria Eradication program (Govt.

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of Haryana and Tamil Nadu) with 72-90% clinical improvement. The response of treatment in double blind controlled study with chloroquine and primaquine as active control, Ayush-64 have shown 89% to 95% of improvement without any side effect.

CCRAS developed has developed a safe herbal Ayurveda drug **Ayush SG (Shunthi Guggulu)**, for the management of Rheumatoid arthritis (Amavata) through series of clinical studies.

Bal Rasayan - Preparation for general resistance in children, AYUSH Ghutti - Preparation for Cough, Cold, Fever & Diarrhea of children, AYUSH-56 - Anti-Epileptic preparation, AYUSH -SS granules - preparation to enhance the quality and quantity of breast milk in mother having deficient lactation, AYUSH AG Tablet - Preparation for Ante Natal Care (Anemia), AYUSH PK Avleha - Preparation for Post Natal Care (to enhance the process of recovery after delivery and other complications of puerperal period), AYUSH PG Tablet - Preparation for Ante Natal Care (Oedema), AYUSH B R Leham - Preparation for Pediatric Care are other leading products by CCRAS.

Drug development studies in progress: CCRAS has undertaken the development of the various coded formulations for different disease conditions.

CCRAS has completed a multi centric clinical study for validation of a coded drug named AYUSH Manas drug for Mental retardation/ cognitive deficit. CCRAS has undertaken work for developing a coded drug named AYUSH QOL 2C for improving Quality of Life of Cancer patients in stage III & IV Non Small Cell Lung Cancer and patients of Local Non-Metastatic Breast Cancer to prevent side effects of Chemotherapy. Collaborative Multi-centric Clinical trial to study the effect of Ayush Rasayana (A&B) on Ageing on apparently healthy elderly subjects is going on at AIIMS New Delhi, IMS BHU and CARIDD Kolkata. Controlled clinical Trial to assess the effectiveness of topical application of C1 herbal oil on superficial external wound and split thickness skin graft donor's site for surgical wound healing at AIMMS New Delhi. CCRAS is working on a collaborative research project for the assessment of safety and efficacy of a coded drug AYUSH PJ-7 for the management of Dengue

Apart from these, collaborative studies are going on for the development of coded drug for several disease of National importance including: AYUSH M-3 for Migraine, AYUSH SL for Filariasis, AYUSH A for Bronchial Asthma, AYUSH D for Type II Diabetes Mellitus, Carctol S for Cancer, AYUSH K1 for Chronic Kidney Diseases which are at different phases of drug development. These studies are being conducted in collaboration with reputed institutes like AIIMS New Delhi, NIMHANS Bengaluru, BHU, ICMR, St. John's Medical College Bengaluru etc.

Evidence Based Safety of Ayurvedic Herbo-mineral Medicines:

The Safety of metal and mineral based Ayurvedic formulations to a large extent is evident by its long history of clinical use and endorsed by recent scientific evidences. Further, the incredible

expansion in the use of Ayurveda worldwide, safety and efficacy as well as quality control have become important concerns for both health authorities and the public, calls for the scientific presentation of facts.

CCRAS has conducted scientific studies in collaboration with reputed institutes to establish safety profiles of *most commonly used Ayurvedic Medicines viz. Rasamanikya, Naga Bhasma, Hridyarnava Rasa, Swarna Bhasma, Tamra Bhasma, Trivanga Bhasma, Makaradhwaja, Rasa Sindoor, Arogyavardhini Vati, Mahalaxmi Vilasa Rasa, Vasanta Kusumakara Rasa, Yogaraja Guggulu, Mahayogaraja Guggulu and Kasisa Bhasma.*

The Ministry of AYUSH, Govt. of India brought out the document "Evidence Based Safety of Ayurvedic Medicines" (2016) and 'Quality and Safety of select Rasakalpa: Metal & mineral based Ayurvedic formulations', in two volumes in 2019 focusing on safety of Ayurvedic metal and mineral based formulations to present the scientific aspects, relevance and rationale of the unique medical interventions.

Conclusion: In order to provide 'Health for all', research including generation of scientific evidence for safety and efficacy from the classical Ayurveda texts, folklores traditions prevalent in India by proper series of research is the most important path to be followed. To achieve this goal, Council is working toward its vision 2030, to develop scientific evidence in Ayurvedic Principles, drug therapies by way of integrating ancient wisdom with modern technology and to bring Ayurveda to the people, through innovations related to diagnostics, preventive, promotive as well as treatment methods. This is done in synergy with concerned organizations to introduce these innovations into public health systems. For this the Council is working towards its sustainable development goals (SDGs) for vision 2030 with a 15 years strategy, 7 years strategy (long-term vision), and 3 years action plan.

The main aim of Translational research is that the findings in basic research are to be translated into medical practice that will lead to meaningful health outcomes.