

**GOVERNMENT OF INDIA
MINISTRY OF AYURVEDA, YOGA & NATUROPATHY,
UNANI, SIDDHA AND HOMOEOPATHY
(AYUSH)**

**LOK SABHA
UNSTARRED QUESTION NO.4524
TO BE ANSWERED ON 12TH AUGUST, 2016**

CLINICAL TRIALS OF TRADITIONAL MEDICINES

**4524. SHRI CHARANJEET SINGH RORI:
SHRIMATI BUTTA RENUKA:**

Will the Minister of **AYURVEDA, YOGA AND NATUROPATHY, UNANI, SIDDHA AND HOMOEOPATHY (AYUSH)** be pleased to state:

- (a) whether the Government has permitted clinical trials of traditional medicines and if so, the details thereof;
- (b) whether the Government proposes to revise the guidelines on clinical trials for new AYUSH drugs including Ayurveda and if so, the details thereof; and
- c) the time by which the revised guidelines on clinical trials for new AYUSH drugs are likely to be implemented?

ANSWER

**THE MINISTER OF STATE (IC) OF THE MINISTRY OF AYURVEDA,
YOGA & NATUROPATHY, UNANI, SIDDHA AND HOMOEOPATHY
(SHRI SHRIPAD YESSO NAIK)**

(a): Drugs & Cosmetics Act, 1940 and Rules thereunder do not have any provisions for clinical trials on traditional medicines. However, on receipt of clinical trial proposals on Ayurvedic and herbal medicines, the then Department of AYUSH granted permission to ten institutes for conducting clinical trials during the period April, 2008 to September, 2010. The details of these clinical trials are annexed.

(b) & (c): New AYUSH drugs including Ayurveda are not defined in the provisions of the Drugs & Cosmetics Act, 1940 and Rules thereunder. The Government published “Good Clinical Practice Guidelines for Clinical Trials in Ayurveda, Siddha and Unani Medicine (GCP-ASU)” in the year 2013 with the objective that the studies are scientifically and ethically sound and the clinical properties of the ASU medicines under investigation are properly documented. The guidelines do not have any legal binding to conduct the clinical trials and no proposal is under consideration to revise them.

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Annexure

Permission granted to the Institutes for conducting Clinical Trials

S No.	Name of the Institution	Subject of Clinical Trial
1.	Indian Institute of Integrative Medicine (IIIM), Jammu:	Proof of Safety and Efficacy Trials on Positive Health Promoter Formulations based on Ayurvedic Plants.
2.	M/s Arvind Remedies and Sri Ramachandra University, Porur, Chennai:	Multicentric Clinical Trial of Herbal Formulation for Management of Cardiovascular and Neurologic Disorders.
3.	Institute of Medical Sciences, Banaras Hindu University and SASTRA University, Thanjavur:	Multicentric Clinical Trial for Prevention and Management of Metabolic Syndrome—an Ayurvedic Intervention.
4.	Institute of Medical Sciences, Banaras Hindu University and SASTRA University, Thanjavur	Prevention and Management of Neuropsychiatric and Cardiovascular Complications among Menopausal Women.
5.	St. Johns Medical College Hospital, Bangalore.	Clinical Trial of Coded Ayurvedic Drug QOL-2C.
6.	Institute of Medical Sciences, Banaras Hindu University & M/s Baijnath Pharmaceuticals, Paprola, Distt. Kangra, Himachal Pradesh.	Multicentric Clinical Trial in Prevention and Management of Type-II Diabetes mellitus and associated vascular complications by a poly-herbal formulation.
7.	National Institute of Mental Health and Neuro Sciences, Bangalore; Dr. RML Hospital, New Delhi and BHU, Varanasi	Clinical trial for effect of Ayurvedic coded drug – Ayushmanas in the management of Manasmandata (Mental Retardation).
8.	Interdisciplinary School of Indian System of Medicine, SRM University, Kancheepuram, Tamil Nadu & Institute of Medical Sciences, Banaras Hindu University, Varanasi	Clinical trial on a Herbal formulation for Prevention and Management of Coronary Heart Disease.
9.	Interdisciplinary School of Indian System of Medicine, SRM University, Tamil Nadu & Institute of Medical Sciences Banaras Hindu University, Varanasi	Multicentric Clinical Trial on Herbal Formulation in the Prevention and Management of Age-related Neurodegenerative Disorders with special reference Senile Dementia of Alzheimer's Type (SDAT).
10.	Interdisciplinary School of Indian System of Medicine, SRM University, Kancheepuram, Tamil Nadu & Institute of Medical Sciences, Banaras Hindu University, Varanasi.	Management of Neuropsychiatric and Cardiovascular Complications among Menopausal Women.

