

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

**LOK SABHA  
STARRED QUESTION NO.67  
TO BE ANSWERED ON 5<sup>TH</sup> FEBRUARY, 2021  
RESEARCH IN AYURVEDIC MEDICINES**

**\*67. DR. SANJEEV KUMAR SINGARI:**

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

(a) whether Government has framed any guidelines for research/clinical trials of Ayurvedic medicines following the rules/protocols set by Organization for Economic Co-operation and Development (OECD), Committee for Purpose of Control and Supervision of Experiments on Animals (CPCSEA) and Institutional Ethics Committee;

(b) whether mandatory registration in Clinical Trials Registry of India is being followed;

(c) if the replies to parts (a) and (b) above be in negative, the steps followed to regulate clinical trials of Ayurvedic drugs in the country;

(d) whether Government has mandated evidence based trials of Ayurvedic drugs prior to their introduction into the market;

(e) if so, the details thereof including the various trials that were conducted during the last six years; and

(f) if not, the reasons therefor including the steps taken to ensure the safety and efficacy of Ayurvedic drugs?

**ANSWER  
THE MINISTER OF STATE(IC) OF THE MINISTRY OF YOUTH  
AFFAIRS AND SPORTS AND ADDITIONAL CHARGE OF  
MINISTER OF STATE (IC) OF THE MINISTRY OF AYURVEDA,  
YOGA & NATUROPATHY, UNANI, SIDDHA AND  
HOMOEOPATHY**

**(SHRI KIREN RIJJU)**

(a) & (f): A statement is laid on the Table of the House

**STATEMENT REFERRED TO IN REPLY TO LOK SABHA  
STARRED QUESTION NO. 67 \* FOR 5<sup>TH</sup> FEBRUARY, 2021**

- a) Yes, Sir. The Ministry of AYUSH has framed Good Clinical Practice guidelines (GCP) for clinical trials in Ayurveda, Siddha and Unani (ASU) medicine in March 2013 with a wide consultative process on the basis of Central Drugs Standard Control Organization's (CDSCO) publication on 'GCP Guidelines for Clinical Trials on Pharmaceutical Products (2001) and imbibes the inputs received from Indian Council of Medical Research (ICMR), CDSCO, Central Councils for Research in ASU systems, experts from Research Institutions, Teaching Institutions, State Regulatory Bodies and representatives from ASU drugs manufacturing industries. As per the rule 1.18 of GCP Guidelines, it is mandatory to have Ethics Committee comprising of medical / scientific and nonmedical / non-scientific members.
- b) Yes, Sir.
- c) Does not arise.
- d) As per rule 158 (B) of the Drugs & Cosmetics Act, 1940, the Ayurvedic formulations/ medicines specified in section 3(a) of Drugs & Cosmetics Act, 1940 require proof of effectiveness to be used for new indication; and for Ayurvedic formulations/ medicines specified in section 3(h) of the Act.
- e) The clinical trials conducted during the last six years are in the areas of Bronchial Asthma (Tamaka Swasa), Essential Hypertension, Anxiety Neurosis, Cervical Spondylosis, Urolithiasis, Uterine Fibroid, Obesity, Computer Vision Syndrome, Menopausal syndrome, Sciatica, Allergic Conjunctivitis, Influenza like Illness, Fissure in Ano, Anorectal Fistula, Allergic Rhinitis, Primary Dysmenorrhoea, leucorrhoea, Malabsorption Syndrome, Dysfunctional Uterine Bleeding, Age Related Macular Degeneration Symptoms, Hyperacidity/Non ulcer dyspepsia, Eczema, Mental retardation (Manasamandata) in children, Local Non-Metastatic Breast Cancer, Dengue Fever, Type 2 Diabetes Mellitus, high grade serous epithelial ovarian cancer, Ante-Natal care, chronic Filarial Lymphoedema, Prevention and Control of Cancer, Diabetes, Cardiovascular diseases & Stroke, COVID-19 etc. The clinical safety and efficacy of around 92 classical formulations in 40 disease conditions has been generated on the basis of preclinical and clinical safety studies as per the guidelines. The details are at annexure-I.
- f) Does not arise.

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**List of Clinical Research Projects conducted during last 6 years (2014-15 to 2019-20)**

**Intra Mural Research Projects**

**Completed**

1. Clinical Evaluation of Vatari Guggulu, Rasna Saptaka Kashaya and Brihat Saindhavadi Taila in the Management of Rheumatoid Arthritis
2. Clinical evaluation of Vatari guggulu, Maharasnadi kwatha and Narayana taila in the management of Osteoarthritis knee.
3. Clinical Evaluation of Ksheerbala Taila Matra Basti, Therapeutic Combination of Vatari Guggulu, Maharasnadi Kwatha and Narayan Taila in the Management of Osteoarthritis Knee
4. A Clinical Evaluation of Efficacy of Classical Ayurvedic Herbo Mineral Formulations in the Management of Arsha (Hemorrhoids)
5. Evaluation of Clinical efficacy and safety of Brahma Rasayana in apparently healthy elderly persons
6. Clinical evaluation of the efficacy of Rajahpravartini vati, Kanchanar guggulu and Varunadi kashaya in the management of Polycystic Ovary Syndrome (PCOS): A pilot study
7. An open label efficacy study of Amrita Guggulu and Pinda Taila in the management of hyperuricemia in Gout (Vatarakta) patients.
8. Clinical Evaluation of Nisha Amalaki and Chandraprabha Vati in the management of Type II Diabetes Mellitus (Madhumeha)
9. Clinical Evaluation of Vajraka Ghritam, Arogyavardhini Vati and Dineshavalyadi taila in the Management of Kitibha (Psoriasis)
10. Clinical Evaluation of Brahma Rasayana in the Management of “Manasa Mandata (Mental Retardation)”- an Open Clinical Trial.
11. Evaluation of clinical efficacy and safety of the Vamana Karma followed by Takradhara and Rasaoushadhi Rasayana chikitsa in Kitibha (Psoriasis)
12. Clinical Evaluation of Nisha Katakadi Kashaya and Yashada Bhasma in the Management of Type II Diabetes Mellitus (Madhumeha)
13. Clinical evaluation of Vasavleha in the management of Stable Chronic Bronchitis
14. Clinical Evaluation of Yogaraj Guggulu, Gandharvahasta Taila and Dhanwantara Taila in the management of Osteoarthritis knee
15. Clinical Evaluation of Kutajarishta In The Management of Irritable Bowel Syndrome (IBS)
16. Clinical evaluation of Sarasvata Ghrita in the management of Cognitive Deficit

17. Clinical evaluation of a Comprehensive Ayurvedic Intervention in the management of Manodwega (Generalized Anxiety Disorder)
18. Clinical evaluation of Vatari Guggulu, Hingvastak Churna and Brihat Saindhavadya Taila in the management of Rheumatoid Arthritis
19. Clinical Evaluation Of Ashwagandha Churna and Pravala Pishti in the Management of Osteopenia / Osteoporosis
20. Clinical evaluation of Navayasa Churna in the management of Iron Deficiency Anaemia
21. Clinical evaluation of Kanakasava and Trivrita Churna in the management of Bronchial Asthma (Tamaka Swasa)
22. Clinical trial to study the Effect of Chyavanprasha on Aging in Apparently Healthy Elderly Subjects
23. Clinical evaluation of Kushmandaka Rasayana in the management of Chronic Bronchitis (Kaphaja Kasa)
24. Clinical evaluation of Gokshuradi Guggulu and Guduchi churna in the management of Madhumeha (Type II Diabetes Mellitus)
25. Clinical evaluation of efficacy of Mahatriphaladi ghritam and Anu taila nasyam in the management of Computer Vision Syndrome
26. Clinical efficacy and safety of Brihat Gangadhara Churna in the management of Irritable Bowel Syndrome.
27. Clinical evaluation of Parthadyarishtha (Arjunarishtha) and Sarpagandha Vati in the management of Essential Hypertension (Uccha Raktachaap)
28. Clinical evaluation of Rudraksha Churna in the management of Essential Hypertension (Uccha Raktachaapa)
29. Clinical evaluation of Vyoshadi Guggulu and Panchasama Churna in Amavata (Rheumatoid Arthritis)
30. Clinical Evaluation of the Efficacy and Safety of Mamajjaka Ghanavati in Madhumeha (Type 2-Diabetes)
31. Clinical Evaluation of Shirodhara with Amalaki Kwath in the Patients of Anxiety Neurosis
32. Comparative Observation on changes in Serum Lipid Profile in patients undergoing Snehana with pure Ghee in one group and Mahatiktak ghrita in other group
33. Effect of Sankara Sweda with Kolakulathadi Churna heated in Dhanyamla, Simhanada Guggulu with Rasna Saptak Kashaya in Rheumatoid Arthritis wrt pain and stiffness
34. Evaluation of the Effect of Upanaha treatment with Vachadi upanaha churna in Osteoarthritis (OA Knee) wrt pain and stiffness of joints (RFD)
35. Evaluation of the effect of Jambheera Pinda Sweda in Cervical Spondylosis w.r.t. Clinical Symptomatology
36. Evaluation of changes in serum electrolyte level (na, k etc.) after Virechan karma with Erandataila.
37. Clinical evaluation of efficacy of Panchtiktaguggulu Ghrita and Brihanmarichadya Taila in the management of Psoriasis w. s. r. to Pathya-apathya

38. Clinical evaluation of Goksura churna and Sveta parpati in the Management of Mutrasmari (Urolithiasis)
39. Clinical evaluation of efficacy of Khadirarishta and Kanchanara guggulu in the management of Uterine Fibroid – An exploratory study
40. Clinical evaluation of Punarnava Guggulu and Rasna Saptaka Kashaya in the management of Rheumatoid Arthritis (Amavata)
41. A Clinical evaluation of Triphala Guggulu and Kasisadi Taila in the management of Arsha (Haemorrhoids)
42. Therapeutic evaluation of Rasnadi Gutika and Chandrakala lepa in Janusandhigata vata (Osteoarthritis)
43. Clinical evaluation of Kaishore Guggulu and Madhusnuhi Rasayana in the management of Gout (Vatarakta)
44. Clinical evaluation of Abhadya Churna and Muktaashukti Bhasma in the management of Osteopenia / Osteoporosis (Asthikshaya)
45. Clinical evaluation of Laksha Guggulu and Muktaashukti Bhasma in the management of Osteopenia/Osteoporosis
46. Clinical Evaluation of Certain Ayurvedic Formulations In The Management of Sthoulya (Obesity)
47. Clinical evaluation of Mandura vataka in the management of Pandu (Iron deficiency Anaemia)
48. Clinical evaluation of Sukumara Ghritam and Brahmi churnam in the management of Menopausal syndrome
49. Clinical evaluation of Kalyanak Ghrita in the management of Cognitive Deficit (Smriti Daurbalya).
50. Clinical evaluation of the efficacy of Trayodashanga Guggulu, Maharasnadi Kwatha and Prasarani Taila in the management of Gridhrasi (Sciatica)
51. Clinical Evaluation of Rasnadi Kvatha churna (Maha), Trayodashanga Guggulu and Brihatsaindhavadya Taila in the Management of Osteoarthritis of Knee (Janugata Sandhivata)
52. Assessment of therapeutic efficacy and safety of Sitopaladi Churna with Madhu in the management of Kasa (Stable Chronic Bronchitis)
53. Clinical efficacy of Talisadi Churna in the management of Kasa (Stable Chronic Bronchitis)
54. Clinical evaluation of Haridrakhand and Triphala Kwath in the management of chronic Allergic Conjunctivitis (Kaphaja Abhishyanda)
55. A Pilot Evaluation of Safety and Efficacy of an Ayurvedic Formulation (AYUSH-64) for accelerating the recovery in cases of Influenza like Illness.
56. Clinical evaluation of Panchamrit Lauha Guggulu and Panchgunataila in the management of Cervical Spondylosis (Greevagraha)
57. Clinical Evaluation of Ayurvedic formulations in the management of Parikartika (Fissure in Ano)
58. Observation on Fistula cutting Time with Ksharsutra used in routine patients of Anorectal Fistula (Bhagandara)
59. Clinical Evaluation of Kantakaryavaleha and Eladi Gutika in the Management of Mild Stable Bronchial Asthma (Tamaka Shwasa)

60. Clinical evaluation of AYUSH-PE eye drops in the management of Acute Allergic Conjunctivitis.
61. Clinical evaluation of an Ayurvedic formulation in the management of Allergic Rhinitis-a pilot study
62. Clinical evaluation of Sapthasaram Kashayam & Saraswatharishtam in the management of Primary Dysmenorrhoea- An Exploratory study
63. Clinical Evaluation of Efficacy of Indukanta Ghrita and Trayodashang Guggulu in the Management of Rheumatoid Arthritis vis –a–vis Amavata.

### **Ongoing**

1. Clinical evaluation of Varunadi Kwath and chandraprabha vati in the management of Mutrasmari (Urolithiasis)
2. Clinical evaluation of Shvadamstradi Kashaya and Hajarulayahud Bhasma in the management of Mutrasmari (Urolithiasis)
3. Clinical efficacy of Kaishore Guggulu and Balaguduchyadi taila in the management of Gout (Vatarakta)
4. Clinical evaluation the efficacy of Pushyanuga Churna in the management of Swetapradra (leucorrhoea) w.s.t. Bacterial Vaginosis
5. Clinical efficacy of Drakshavelaha in the management of Pandu (Iron Deficiency Anemia)
6. Clinical efficacy of Drakshasava in the management of Pandu (Iron Deficiency Anemia)
7. Clinical evaluation of Eladi Churna and Draksharishta in the management of Kasa
8. Clinical Evaluation of Varunadi Kwanth Churna and Apamarga Kshara in the Management of Mutrashmari (Urolithiasis)
9. Clinical evaluation of Shadbindu Taila Nasya and Chitraka Haritaki in the management of Pinasa (Chronic Rhinosinusitis)
10. A clinical study on efficacy and safety of an Ayurvedic formulation Kutajavleha in the management of Grahani
11. Clinical evaluation of Pathyadi Kwatha and Anu Taila Nasya in the management of Migraine
12. Clinical evaluation of Chitrak Haritaki and Lavangadi Vati in the management of Kaphaja Kasa (Stable Chronic Bronchitis)
13. Clinical evaluation off Agashtya haritaki Rasayana and Apamarga Kshara in the management of mild stable Bronchial Asthma
14. A Clinical evaluation of Jirakadyarishta in the management of Mutrasmari (Urolithiasis)
15. Clinical evaluation of Mustakarishtha in the management of Grahani (Malabsorption Syndrome)
16. Randomised placebo controlled double blind clinical trial on the efficacy of AYUSH MANAS in the management of Smriti Dourbalya (Cognitive deficit)

17. Clinical Evaluation of the effect of Satavari Guda in the management of Dysfunctional Uterine Bleeding (Asrigdara)
18. Clinical evaluation of the efficacy of Pushyanuga Churna and Ushirasava in the management of Asrigdara (Dysfunctional Uterine Bleeding)
19. Clinical Evaluation of Triphala Ghrita as topical (Tarpana) and internal medication in the management of Dry Age Related Macular Degeneration Symptoms.
20. Clinical evaluation of Narikela Lavana and Amalaki Churna in management of Amlapitta (Hyperacidity/Non ulcer dyspepsia)
21. Clinical evaluation of Panchatikta Ghrita and Nalpamaradi Taila in the management of Vicharchika (Eczema)
22. Efficacy of Ayurvedic intervention in the management of occupational stress among IT professionals.
23. Clinical evaluation of Panchatikta Ghrita & Nalapamaradi taila in the management of Psoriasis (Kitibha)
24. Clinical evaluation of Jatiphaladya Churna & Chitrakadi Gutika in the management of Grahani (Malabsorption Syndrome)
25. Clinical evaluation of Panchatikta Ghrita and Gandhakadya Malahara in the management of Vicharchika (Eczema)

### **Collaborative Clinical Research Projects**

#### **Completed**

1. Multi-centric double blind randomized controlled clinical trial of coded drug AYUSH-Manas in Mental retardation (Manasa mandata) in children
2. A Pilot Study Evaluating Quality of Life with AYUSH QOL – 2C in Patients of Local Non-Metastatic Breast Cancer Treated with Adjuvant Chemotherapy/Radiotherapy and Correlating it with Molecular Marker.
3. Collaborative Multicentric Clinical Trial to Study the Effect of Ayush Rasayana (A&B) on Ageing in Apparently Healthy Elderly Subjects
4. Comparative clinical evaluation of Ksharasutra prepared manually and by automated machine in fistula-in-ano (Bhagandara)
5. Development and validation of Prakriti Assessment Questionnaire/ Scale
6. Controlled Clinical Trial to assess the effectiveness of topical application of C 1 herbal oil on superficial external wound and split thickness skin graft donor's site for surgical wound healing

#### **Ongoing**

1. Evaluation of Add on Efficacy & Safety of an Ayurvedic coded Formulation in the management of Dengue Fever & Prevention of its complications
2. A Randomized Placebo Controlled Prospective Phase II Clinical Study of an Ayurvedic Coded Drug 'AYUSH-D' on Glycemic control in Pre-Diabetic Subjects (Collaborative)

3. A Randomized Placebo Controlled Prospective Phase II Clinical Study of an Ayurvedic Coded Drug 'AYUSH-D' in the management of Type 2 Diabetes Mellitus as add on Therapy to Metformin (Collaborative)
4. Validation and Reliability Testing of Ayurveda Diagnostic Methods
5. A phase II trial to study efficacy, toxicity and immunomodulatory effect of Carctol-S in high grade serous epithelial ovarian cancer at first serological relapse collaborative project.
6. Feasibility of introducing Ayurveda intervention in Reproductive and Child Health (RCH) in PHCs of selected district of Maharashtra (effectiveness of Ayurvedic intervention for Ante-Natal care (Garbhini Paricharya) at Primary Health Care Level: A Multi-Centre Operational Study).
7. Multi-centric collaborative Placebo controlled study on clinical evaluation of Ayush SL in chronic Filarial Lymphoedema in patients receiving mass drug administration.
8. CSIR-Central Institute of Medicinal & Aromatic Plants (CSIR-CIMAP), Lucknow; and CSIR-National Botanical Research Institute (CSIR-NBRI), Lucknow had taken up trial on a proprietary anti-diabetic formulation at Banaras Hindu University, Banaras.
9. CSIR-Indian Institute of Integrative Medicine (CSIR-IIIM), Jammu and Central Council of Research in Ayurveda Sciences (CCRAS) are conducting following studies:
  - Ashwagandha for the Prophylaxis against SARS-CoV-2 Infection: A Randomized Hydroxychloroquine Controlled Clinical Trial in Health Care Providers;
  - A Randomized, Open Label, Parallel Efficacy, Active Control, Multi-Centre Exploratory Drug Trial to Evaluate Efficacy and Safety of Ayurvedic formulation-2 (*T. cordifolia* + *P. longum*) as Adjunct Treatment to Standard of Care for the management of Mild to Moderate COVID-19 Patients; and
  - A Randomized, Open Label, Parallel Efficacy, Active Control, Multi-Centre Exploratory Drug Trial to Evaluate Efficacy and Safety of Ayurvedic formulation-3 (Glycyrrhizaglabra) as Adjunct Treatment to Standard of Care for the management of Mild to Moderate COVID-19 Patients.