अखिल भारतीय आयुर्विज्ञान संस्थान, नागपुर
ALL INDIA INSTITUTE OF MEDICAL SCIENCES, NAGPUR
Address: Plot No. 2, Sector-20, MIHAN, Nagpur – 441108
Email: drkprathipati@aiimsnagpur.edu.in
DEPARTMENT OF ENT

AIIMS-NAG/ENT/2025/1090 Date: 16/12/2025

NOTICE INVITING QUOTATIONS

The Executive Director, All India Institute of Medical Sciences (AIIMS), Nagpur invites quotations from interested Indian insurance agencies or intermediaries (Agents, Brokers, Corporate Agents, Insurance POS, or individuals working with brokers, etc.) for providing Clinical Trials Liability Insurance coverage for patients participating in the ICMR-AYUSH funded AYURCAN Trial."

Please mention the details as follows:-

Particular	Limit of liability for death claim, per subject and in aggregate	Deductible for death claim	Medical expense per subject and in aggregate	Deductible for medical expense	Annual Premium without GST for ~~first~~ one year	Annual Premium with GST for ~~first~~ one year
Clinical Trials Liability Insurance Coverage – AYURCAN Trial						
Extended Reporting period						

In accordance with regulatory and ethical requirements (as per ICMR and GCP guidelines), we seek to secure insurance coverage for all enrolled participants to cover risk safety against any trial-related injury or serious adverse event (SAE). The technical specifications for the same are mentioned in Annexure I.

Clinical trial insurance for the following is required: Compensation for "Trial related injuries' for study participants as per 'New Drugs and Clinical Trials Rules, 2019, [G.S.R. 227(E)] dated 19 March 2019' and medical management for adverse events related to study intervention and not natural disease progression.

The interested insurance companies or agencies on behalf of insurance companies should prescribe the conditions and extent of coverage, date of commencement and expiry of coverage thereof, including the premium and other costs, as per rules for the aforementioned study.

TERMS OF CONDITIONS:

1. All quotations to be submitted in the name of Executive Director, AIIMS Nagpur only. Quotations not addressed to Executive Director, AIIMS, Nagpur will not be opened and rejected summarily.
2. Vendors are requested to submit detailed technical specification of quote along with brochure approved with IRDA, if available.
3. Quotations without technical specification will be strictly rejected
4. Premium amount to be quoted annually along with GST.
5. Premium amount will be paid on an annual basis.
6. Bank details such as Account Number, IFSC Code etc. should be furnished so as to facilitate payment of premium on acceptance of quote and release of work order.
7. A declaration by the vendor is required to be submitted along with a quotation station that the vendor is not debarred by the Department of Commerce or Ministry/ Department concerned. The date of declaration should not be before the date of NIQ and after the last date of submission of quotation.
8. The Agency should be able to have a qualified medical practitioner (minimum MBBS) to coordinate with the clinical team for any insurance support.

9. Rights to accept/reject any quotation rests with the AIIMS Nagpur. Please email the quotation with complete documentation to drpkprathipati@aiimsnagpur.edu.in.

Please email on the above-mentioned email address if you need any further clarification.

Please submit the hard copy of the quotations in sealed envelope to following address: "Store office, Admin block, AIIMS Nagpur, MIHAN, Plot No 2 Sector 20 MIHAN Nagpur.", super scribing: - **"Quotation for Clinical Trials Liability Insurance Coverage- AYURCAN TRIAL, Department of ENT, AIIMS Nagpur"** w.r.t. NIQ No. AIIMS/NGP/ENT/AYURCAN TRIAL/ , dated:22/12/2025" on or before 23/12/2025 before 17.00hrs, which will be opened on / /2025 at 11.00 hrs.

16/12/25

Administrative officer -I
AIIMS Nagpur

रोहन एल. बागडे / Rohan L. Bagde
प्रशासनिक अधिकारी / Administrative Officer
अ.भा.आ.सं. नागपुर / AIIMS, Nagpur

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Annexure I

Technical Specification of policy

Trial Title:
"A Single-center, Investigator-blinded, Randomized, 24-month, Parallel-group, Non-inferiority Study to Compare the Efficacy of Combination of Ayurvedic Therapy as Add-on treatment Versus Standard treatment in Oral Pre-malignant Lesions and Early Oral Cancer."- AYURCAN TRIAL

1. Trial Governance

- Academic clinical trial conducted by **AIIMS Nagpur**
- Funded by **ICMR,CCRAS**
- Approved by the **Institutional Ethics Committee (IEC)**
- Registered with **Clinical Trials Registry of India (CTRI/2025/03/083289)**

2. Trial Design

1.Randomized controlled, assessor-blinded, parallel-group design
2.Duration: **2 years (24 months)**
3.Recruitment: **338 participants** across three subgroups

3. Participant Subgroups

- Premalignant lesions (Leukoplakia, Erythroplakia): **172 patients**
- Oral Submucous Fibrosis: **100 patients**
- Early Oral Cancer: **66 patients**

4. Recruitment & Screening

Source: ENT Outpatient Department (OPD), AIIMS Nagpur

Screening includes:
1.Clinical evaluation
2.Hematological investigations
3.Radiographic/imaging studies
4.Histopathological confirmation where required
5.Inclusion/Exclusion applied strictly before enrolment

5. Interventions

Control Arm (Standard Treatment):
1. Betel nut/areca nut/quid/tobacco cessation
2. Dietary modification for 3 months

Intervention Arm (Standard + Ayurveda Add-on):

1. Same Standard Treatment
2. Ayurvedic therapy (3 months)

6. Assessments

Regular evaluations by clinicians and Ayurvedic experts
Tools:

Biomarkers: Ki67, COX2, P53

1.Symptom scores: Visual Analogue Scale (VAS)
2.Mouth opening: Inter-incisal distance (in OSMF)
3.Lesion monitoring: Size and appearance (in leukoplakia/erythroplakia)
Imaging, clinical photos, and biomarker sampling at baseline and follow-up

7. Expected Outcomes

Evidence generation for Ayurveda's role in:

1.Prevention of malignant transformation
2.Symptom relief and functional improvement
3.Scientific rationale for integration of Ayurveda in cancer care

8. Follow-up & Duration

Individual follow-up: **3 months**
Overall study period: **24 months (2 years)**

9. Insurance Requirement

Patient recruitment will commence only after trial insurance policy is obtained.

Sr. No.	Item	Specifications
1)	Phase of trial and sponsor	Phase III Academic Clinical trial sponsored by Indian Council of Medical Research (ICMR), New Delhi
2)	Site of the trial	AIIMS Nagpur
3)	Sample size	338 (172 in Premalignant group – 86 per arm; 100 in Submucous Fibrosis – 50 per arm; 66 in Early Oral Cancer – 33 per arm). Recruitment will be done prospectively from ENT OPD after screening as per inclusion/exclusion criteria.
4)	Minimum limit of liability	1 Crore per subject and in aggregate annually. AOA:AOY = 1:1
5)	Medical Expense	INR 25 thousand / INR 50 thousand per subject and INR 3 lakh / INR 6 lakh in aggregate annually

6)	Reporting period for submitting claims	1. The reporting period for submitting claim for compensation for death or SAE other than death will ordinarily be in the 12-month annual policy period, within which the SAE or death occurred, irrespective of the date of enrolment of the subject. 2. The reporting period for submitting a claim for legal costs will ordinarily be in the 12-month annual policy period, within which the legal cost was incurred, irrespective of the date of enrolment of the subject.
7)	Extended reporting period	To account for death, SAE or legal costs incurred towards the end of a 12-month annual policy period, an extended reporting period of 6 months must be provided after the end of each annual policy period during which time a claim of death, SAE or legal costs can be notified.
8)	Deductibles	1. For medical claims, the deductible will not exceed **INR 10,000** per claim. 2. For liability claims, the deductible will be **INR 1,00,000 or 10% of the claim amount, whichever is lower**, subject to an aggregate upper limit of **INR 1 lakh per annum or less**, irrespective of the number of patients or the total amount claimed within the AOY, AOA and per-patient sub-limit.
9)	Authority that will decide whether death or SAE is related to participation in the clinical trial	1. Whether an enrolled patient's SAE or death is related to the clinical trial will solely be determined by the Data Safety Monitoring Committee and Institutional Ethics Committee. 2. The vendor will have no authority to decide on matters of relationship of the SAE or death to the trial.
10)	Renewal of insurance cover	1. Insurance cover will be renewed on an annual basis for 3 years or more if trial extended. But assured renewal for 3 yrs is must at same terms and conditions. 2. The Insurance company/Vendor will not refuse renewal on account of claims if any in the preceding year.
11)	Legal liability coverage	1. Vendor will provide Professional Indemnification for all the Investigators, physicians, nurses, research staff and the trial site. 2. Vendor will provide legal liability cover for all the research investigators, the sponsor (ICMR and CCRAS New Delhi), institutional ethics committee members, all research staff employed under the project, subject to the below mentioned points: a) The policy will cover the costs resulting due to legal cases arising from the conduct of the study. b) The coverage will be extended to include negligent act, error or omission of the insured in rendering or failure to render medical professional services to the enrolled patient during the period that the patient was in the clinical trial, which may result in or may result in the adverse event or death of the patient. c) Legal defense costs will be included within the per patient sub-limit of liability, i.e. the sub-limit will include both the compensation to patients for death or SAE as well as legal defense costs. d) Time limit for submitting claim for legal defense costs: any time within the 12-month policy period that the legal defense cost was incurred, irrespective of the time period when the concerned patient actually suffered a SAE or death plus the extended reporting period.

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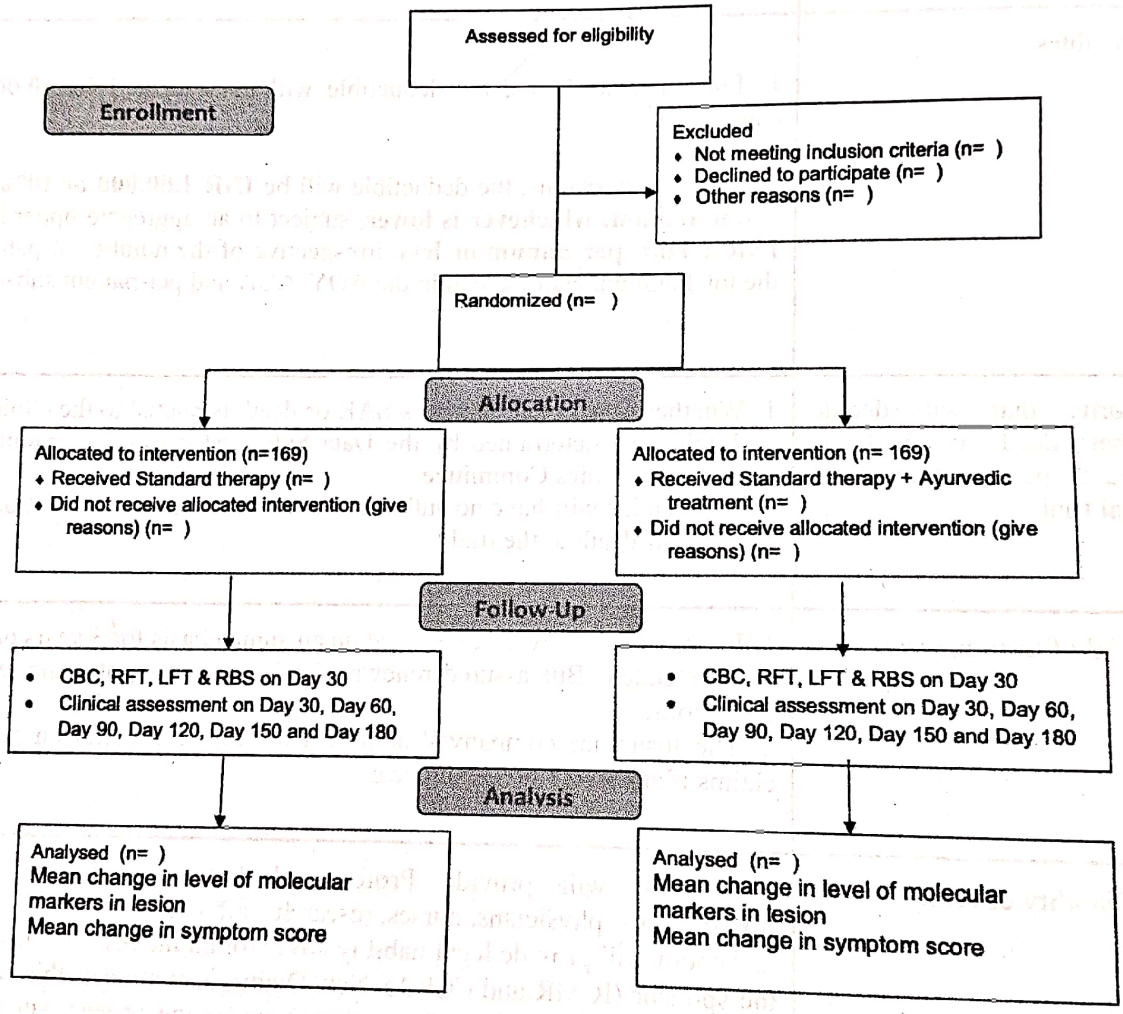
CONSORT Diagram



Protocol Summary