Cover Page

Official Study Title:

ExteNT N0 Trial- Extent of Neck Treatment in clinically N0 oral cancer: A Randomized Controlled Trial

ClinicalTrials.gov Identifier (NCT Number): Pending (To be assigned)

Document: Study Protocol (Version 1.0)

Document Date: 01 April 2026

KOLHAPUR CANCER CENTRE, KOLHAPUR

Institutional Ethics Committee (IEC)

PATIENT INFORMATION SHEET (ENGLISH)

EXTENT N0 Trial

Extent of Neck Treatment in Clinically N0 Oral Cancer: A Randomized Controlled Study

Principal Investigator: Dr. Maroti Wadewale (8483851334) and Dr Parag Watve
Department: Head and Neck Surgical Oncology
Institution: Kolhapur Cancer Centre, Kolhapur
Protocol Version/Date: _____
IEC Approval No.: _____

UHID		Study no	
Name			
Age/Sex			

You are being invited to participate in a research study comparing two accepted neck dissection procedures for oral cancer with clinically N0 neck.

Procedures
Group A: Levels I–III neck dissection
Group B: Levels I–IV neck dissection
Assignment by computer randomization
Regular follow-up for 3-5 years

Risks
Pain, bleeding, infection, shoulder weakness, chyle leak, numbness, and other routine surgical complications.

Benefits
Possible better cancer control and contribution to future treatment guidelines.

Compensation for Study-Related Injury (ICMR Clause)

In the event of any study-related injury, harm, disability, or death, the participant shall be entitled to compensation as per ICMR National Ethical Guidelines and applicable CDSCO / DCGI regulations. Compensation will be provided according to the decision of the Institutional Ethics Committee and competent authority.

Confidentiality
All personal and medical information will remain confidential.

Voluntary Participation
Participation is voluntary and withdrawal can be done at any time without affecting treatment.

I have read / been explained the study information in a language I understand. I voluntarily agree to participate.

Patient Name: _____
Signature / Thumb impression: _____
Date: _____ Time: _____

Investigator Signature: _____
Date: _____

Witness Signature: _____
Date: _____