The Role of Neo-adjuvant Chemotherapy for Mandibular Preservation in Locally Advanced Operable Squamous Cell Carcinoma of the Oral Cavity – A Phase II RCT.

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Conclusion

• Neo-adjuvant chemotherapy appears to be a feasible option for mandibular preservation (48%), in a select group of patients.

• We have proposed a Phase-III trial based on these results.

Images

- Before NACT
  - Paramandibular disease
  - Requiring segmental resection

- After NACT
  - Reduced tumour size enables marginal mandibulectomy

Introduction

Aim Of the study: To evaluate the role of NACT in Mandible Preservation

Objectives:
• Primary: Mandible Preservation
• Secondary:
  • Quality of life
  • Loco regional control

Eligibility Criteria:
• Inclusion
  • Advanced oral cancers
  • No bony invasion
  • Requiring segmental mandibular resection
  • Adequate organ function to receive chemotherapy
• Exclusion
  • Presence of Mandibular erosion
  • Unfit for chemotherapy
  • Refusal to give informed consent

Mandible Preservation

• Intervention Arm
  • 48% (16/34)

Survival – DFS & OS

Median Follow up (26.5 months)

Future..

• A Prospective Phase III open label Randomized Controlled Trial evaluating the role of Neo-adjuvant chemotherapy in mandible preservation in oral cavity cancers.
  • Study (Multicentric) is about to be initiated.
  • Primary End Point: Disease free Survival.
  • Sample Size: 284 patients (142 in each group).