

Validation of the O-bridge Protocol: a Prospective, Multicenter Trial

NCT04007783

Status RECRUITING
Sponsor AZ Sint-Jan AV
Enrollment 80 participants

Key Eligibility Criteria

Inclusion (3)

- Patients with a histologically or clinically confirmed diagnosis of ORN, MRONJ, as classified by respectively Lyons et al. (Lyons, et al., 2014) and Ruggiero et al. (Ruggiero, et al., 2009) (Ruggiero, et al., 2014) or a benign or malignant tumour located in the oral cavity and jaw bone (NCCN, 2015) (Sobin, et al., 2009), requiring marginal, segmental or total jaw resection
- Patients eligible for jaw and oral cavity reconstruction combined with immediate/delayed implant loading for fixed prosthetic rehabilitation
- Patients not eligible for conventional removable prosthetic rehabilitation

Exclusion (4)

- Patients not eligible to the abovementioned criteria
- Patients with a clinically confirmed diagnosis of osteonecrosis not related to an oncological diagnosis or treatment
- Patients with medical contraindications for jaw reconstruction combined with immediate implant loading for fixed prosthetic rehabilitation
- Patients whose maternal language is non-Dutch or non-English will be excluded from the acoustic speech evaluation. A perceptual evaluation of speech intelligibility can still be performed.

Locations (5 total)

Ziekenhuis Netwerk Antwerpen, Antwerp, Belgium
ZMACK association - Antwerp University Hospital, Antwerp, Belgium
Division of Oral and Maxillofacial Surgery, Department of Surgery, AZ Sint-Jan Brugge-Oostende AV, Bruges, Belgium
... and 2 more locations

<https://clinicaltrials.gov/study/NCT04007783>

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