Improved implant for reconstruction purposes after mandibular resection

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON50065

Source
ToetsingOnline

Brief title
RIfRaM

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified
- Head and neck therapeutic procedures

Synonym
Head and Neck Cancer, Oral cavity tumour, Tumour with mandible invasion

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: TKI Health Holland - projectcode LSHM19085

Intervention

Keyword: COMMANDO, Head and neck cancer, Mandibula reconstruction, Patient specific implant

Outcome measures

Primary outcome

The study endpoint is to use the RIfRaM without any complications and a perfect

mandibular fit.

Secondary outcome

Opinions of the surgeons using the implant will be collected in a

non-structured form.

Study description

Background summary

This study concerns patients with oral cancer which also includes the mandible, a part of the mandible should therefor be resected i.e. segmental mandibulectomy. Because of the central role of the mandible in essential functions such as mastication, swallowing, speaking, as well as the aesthetic definition of the face, it must be reconstructed. The standard reconstruction is usually a free bone flap such as a free fibula or iliac crest flap, and a medically competent titanium plate is used to connect the bony segments. Some ~40% of the patients are ineligible for such delicate, toilsome operation due to the conditions of their lower leg and neck vasculature, chronic diseases, and or general health. These patients only receive a titanium plate instead of and a local/regional flap to bridge the defect. In time, it was discovered that these titanium plates were loosening as a result of radio-osteonecrosis, infections, and having a tendency to bend or break. A recent review of our own records show that these complications occur in ~40% of the cases leading to loss of the reconstruction plate. Therefore leading to secondary repair surgery. In order to solve this difficulty, the clinical expertise of AVL-NKI and Mobius 3D Technologies joined forces to develop the RIfRaM. RIfRaM is a patient specifically designed light-weighted 3D printed titanium implant for those who are not eligible for mandibular reconstruction with fibula bone free flaps. It has been designed as a light implant that can bear the mastication force while conserving the patient-specific aesthetic contouring. RIfRaM usage

is aimed to avert the complications of conventional implants such as breaking and loosening and therefore giving the patient of the long lasting benefit of the treatment.

Study objective

The aim is to provide enough evidence through RifRam model analysis, physical tests and clinical study of 10 patients that our new type of personalized mandibular implant is safe to use, resulting in significantly fewer complications and can be practically placed during the surgery, without any complications.

Study design

A non-randomized, prospective clinical feasibility study.

Study burden and risks

Since 3D printed medical-grade titanium medical implants are already being used at the AvL, there should be no additional risks to the patient other than the risks involved with the standard procedure of using titanium plates. Conventional plates are still available for use in case the innovative RifRam implant appears be not feasible during surgery.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Age >= 18 years at time of study entry.
• T4 oral cavity tumor with mandible invasion, requiring segmental mandibulectomy.
• Reconstruction with free fibula flap not feasible because of any or a combination of the following reasons::
o CT angiography of the legs and/or the neck shows severe stenosis of the ves-sels.
o Previous medical history of severe atherosclerotic disease.
o General health condition necessitating a shorter operation time.
• Cases will be discussed in the multidisciplinary tumor board that they are eligible for composite resection but not eligible for free fibula flap.
• Written informed consent.

Exclusion criteria

• Patients who are eligible for free fibula flap.
• Pregnancy.
• General health condition does not allow surgery
• History of psychiatric disability judged by the investigator to potentially hamper compliance with the study protocol and follow-up schedule.
• Any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-02-2022
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	RifRam implant
Registration:	No

Ethics review

Approved WMO

Date:	06-01-2021
Application type:	First submission
Review commission:	METC NedMec

Approved WMO

Date:	11-11-2021
Application type:	Amendment
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL74131.031.20