

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of effect of using synthetic membrane for plates of reconstructing mandible on frequency of exposure

Protocol summary

Summary

Mandibular reconstruction plates have revolutionized the treatment of mandibular continuity defects following ablative or trauma surgery. Plate exposure is one of the most serious complications in mandibular reconstruction field. Plate exposure is closely associated with patients who received radiation therapy, and have lateral defects reconstructed with a plate only or plate/flap reconstruction. Our hypothesis was based on adding a synthetic barrier between soft tissue and reconstruction plate. This kind of isolation is routine in reconstructive field of orthopedic surgery with synthetic barrier that have been called "attachment tube. This polyethyleneterephthalat(PET)tube(MUTARS®, Implant cast GmbH) allows for reconstruction of the capsule and refixation of the muscles and helps minimize dislocation when it is used in proximal treatments of the homeruns(rotator cuff) and femur. Patients between 20 and 70 with partial mandibulectomy due to malignant tumor, underwent reconstruction with RP and membrane or reconstruction plate and membranre and free vascular flap. These patients will have at least 30 session radiotherapy after surgical procedure. These patients will have 2 years follow up for evaluating plate exposure.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201211065496N2**
Registration date: **2012-12-05, 1391/09/15**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-12-05, 1391/09/15

Registrant information

Name

Ata Garajei

Name of organization / entity

Tehran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences, Vice- Chancellor for Research, Craniomaxillofacial Research Center

Expected recruitment start date

2013-01-20, 1391/11/01

Expected recruitment end date

2014-01-21, 1392/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of effect of using synthetic membrane for plates of reconstructing mandible on frequency of exposure

Public title

Evaluation of effect of using synthetic barrier for plates of reconstructing mandible on frequency of exposure

Purpose

Treatment

Inclusion/Exclusion criteria

Patients between 20 and 70 with partial mandibulectomy due to malignant tumor, underwent reconstruction with

reconstruction plate and membrane or reconstruction plate and membranre and free vascular flap. These patients will have at least 30 session radiotherapy after surgical procedure.

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Keshavarz Blvd

City

Tehran

Postal code

Approval date

2012-11-10, 1391/08/20

Ethics committee reference number

90-04-106-16129-69824

Health conditions studied

1

Description of health condition studied

Mandibular Reconstruction

ICD-10 code

Z42.0

ICD-10 code description

Follow-up care involving plastic surgery of head and neck

Primary outcomes

1

Description

Plate Exposure

Timepoint

Three monthly

Method of measurement

Observation by one fix observer

Secondary outcomes

1

Description

Infection

Timepoint

Monthly

Method of measurement

Observation of pus and other sistemic sign and symptom

2

Description

Recurrence of primary tumor

Timepoint

Monthly

Method of measurement

Observation any sign presentig recurrence

Intervention groups

1

Description

adding a synthetic barrier between soft tissue and reconstruction plate.This kind of isolation is routine in reconstructive field of orthopedic surgery with synthetic barrier that have been called "attachment tube".

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Cancer Institute

Full name of responsible person

Ata Garajei

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2

Recruitment center

Name of recruitment center

Shariati Hospital, Department of Oral and Maxillofacial Surgery

Full name of responsible person

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Shariati Hospital, Department of Oral and Maxillofacial Surgery

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armita85@yahoo.com

Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Craniofacial Research Center, Tehran University of Medical Sciences

Full name of responsible person

Dr Mohammad Bayat

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Shariati Hospital, Department of Oral and Maxillofacial surgery

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Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Craniofacial Research Center, Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector*empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Person responsible for general inquiries****Contact****Name of organization / entity**

Craniofacial Research Center

Full name of responsible person

Dr Armita Arvin

Position

Dentist

Other areas of specialty/work**Street address**

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Tehran university of Medical Sciences

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Web page address<http://www.tums.ac.ir/faculties/atagarajei>**Sharing plan****Deidentified Individual Participant Data Set (IPD)***empty***Study Protocol***empty*

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty