

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

The comparison of tapered versus cylindrical implants in post-operative pain amount after dental implant surgery in posterior maxilla.

Protocol summary

Study aim

The comparison of tapered versus cylindrical implants in post-operative pain amount after dental implant surgery in posterior maxilla.

Design

The randomized triple-blinded single center clinical trial with parallel groups, without the placebo. Sample size: 60 patients Randomization method: A concealed simple randomization with randomized numbers table.

Settings and conduct

Setting and conduct of the trial: Oral and maxillofacial surgery department of mashhad dental school.

Blinding: The participants (patients), investigator who collects data and assessors the outcome and who analyses the data would be blind to the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The age between 20-50 years old, the healthy systemic physical status (ASA I,II) without the history of analgesic and sedative drugs in the past 1 year, candidate for 1 or 2 units implantation in posterior maxilla region, existing the sufficient bone width and height in posterior maxilla region and lack of need for bone graft and sinus lift during implantation Exclusion criteria: Patients who would not attend for follow up sessions and arbitrary usage of analgesic drugs except Gelofer by patients, because of intolerable severe pain

Intervention groups

Intervention group 1: Tapered implant Intervention group 2: Cylindrical implant No control group

Main outcome variables

Main outcome: Postoperative pain amount after implant surgery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150613022697N4**

Registration date: **2018-06-16, 1397/03/26**

Registration timing: **prospective**

Last update: **2018-06-16, 1397/03/26**

Update count: **0**

Registration date

2018-06-16, 1397/03/26

Registrant information

Name

Sahand Samiee rad

Name of organization / entity

mashhad dental school, oral and maxillofacial department

Country

Iran (Islamic Republic of)

Phone

+98 51 3883 7289

Email address

samieerads@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-22, 1397/04/01

Expected recruitment end date

2019-05-22, 1398/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of tapered versus cylindrical implants in post-operative pain amount after dental implant surgery in posterior maxilla.

Public title

Post-operative pain amount in tapered versus cylindrical implants

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The age between 20-50 years old The healthy systemic physical status (ASA I,II) Without the history of analgesic and sedative drugs in the past 1 year. Candidates for 1 or 2 units implantation in posterior maxilla region Existing the sufficient bone width and height in posterior maxilla region lack of need for bone graft and sinus lift during implantation

Exclusion criteria:

Patients who would not attend for follow up sessions. The arbitrary usage of analgesic drugs except Gelofen by patients, because of intolerable severe pain.

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple individual randomization using the table of random numbers would be used. Allocation concealment of random codes would be carried out.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The participants (patients), investigator who collects data and assessors the outcome and the statistician who will analyse the data would be blind to the study. the patients who participated in this study do not know which kind of same size implants whether cylindrical or taper would be used for them. the pain assessor would be another surgeon who is blind to the study.

Placebo

Not used

Assignment

Parallel

Other design features

The randomized triple blind clinical trial without the placebo

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad university of medical sciences

Street address

Ghoreishi building, Daneshgah avenue

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Approval date

2018-04-18, 1397/01/29

Ethics committee reference number

IR.MUMS.DENTISTRY.REC.1397.007

Health conditions studied

1

Description of health condition studied

Dental implant surgery

ICD-10 code

M27.69

ICD-10 code description

Other endosseous dental implant failure

2

Description of health condition studied

Post-operative pain

ICD-10 code

G89.11

ICD-10 code description

Acute pain due to trauma

Primary outcomes

1

Description

The post-operative pain amount

Timepoint

In 3,6 and 12 hours after the surgery and also in 1,2,3 and 7 days post-operatively.

Method of measurement

The score of 0 to 10 by VAS system (Visual Analog Scale)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Tapered implant with 4mm diameter from Biohorizone system which needs drilling

regarding the tapered system protocol.

Category

Treatment - Surgery

2**Description**

Intervention group 2: Cylindrical implant with 4mm diameter from Biohorizone system which needs drilling regarding the straight system protocol.

Category

Treatment - Surgery

Recruitment centers**1****Recruitment center****Name of recruitment center**

Oral and maxillofacial surgery department, Mashhad dental school.

Full name of responsible person

Sahand Samiee rad

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Vakil abad street, Mashhad dental school

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

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

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Sahand Samiee rad

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Latest degree

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Other areas of specialty/work

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All collected deidentified data would be shared for all researchers.

When the data will become available and for how long

The access to data will be started 6 months after publication.

To whom data/document is available

The data would only be available for people working in academic institutions.

Under which criteria data/document could be used

It is allowed to use the data for meta-analysis and systematic reviews.

From where data/document is obtainable

The data can be obtained via email, from the corresponding researches (Dr Sahand samiee rad). E-mail: samieerads@mums.ac.ir

What processes are involved for a request to access data/document

The new research proposal and the processes details should be e-mailed to corresponding researcher in order to get the access permission.

Comments