

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of open Sinus Lift by Piezosurgery and Conventional Rotative Instruments in terms of surgical time, edema and pain

Protocol summary

Study aim

Comparison of open Sinus Lift by Piezosurgery and Conventional Rotative Instruments in terms of surgical time, edema and pain

Design

Clinical trials with a control group, with parallel groups, single-blind, randomized. Surgical areas are randomly divided into two groups by www.randomization.com site.

Settings and conduct

The study will be conducted on patients referring to the periodontics department of Mashhad Dental School, who are requiring dental implant in the posterior maxillary region (residual alveolar bone height, 5 mm or less bilateral). Sampling will be done randomly and for each treatment group, 15 samples and a total of 30 samples will be considered. Outcome measurer of this study will be blind (double-blind).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age over 18 years, At least 4 months after tooth loss, requiring dental implant in the posterior maxillary region (residual alveolar bone height, 5 mm or less bilateral) Signature of consent form exclusion criteria: History of Bone Metabolic Diseases, smoking, Contraindications for implant placement, Immune system defects, Infection in maxillary region, Sinusitis, Endocarditis, Sensitivity to penicillin and its derivatives, Destructive parafunctional habits, requiring Advanced Bone Surgery or Ridge Augmentation, Pregnancy and lactation, Uncontrolled diabetes

Intervention groups

Control group: open sinus lift surgery using rotative diamond burs , Intervention group: open sinus lift surgery using Piezosurgery

Main outcome variables

Clinical parameters include: postoperative pain and edema and time during surgery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150504022085N2**

Registration date: **2020-03-27, 1399/01/08**

Registration timing: **retrospective**

Last update: **2020-03-27, 1399/01/08**

Update count: **0**

Registration date

2020-03-27, 1399/01/08

Registrant information

Name

Reza Shahakbari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3765 1793

Email address

shahakbarir@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-05, 1398/02/15

Expected recruitment end date

2019-05-23, 1398/03/02

Actual recruitment start date

2019-05-05, 1398/02/15

Actual recruitment end date

2019-05-23, 1398/03/02

Trial completion date

2019-05-23, 1398/03/02

Scientific title

Comparison of open Sinus Lift by Piezosurgery and Conventional Rotative Instruments in terms of surgical time, edema and pain

Public title

Comparison of open Sinus Lift by Piezosurgery and Conventional Rotative Instruments

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 18 years At least 4 months after tooth loss requiring dental implant in the posterior maxillary region (residual alveolar bone height, 5 mm or less bilateral) Signature of consent form

Exclusion criteria:

History of Bone Metabolic Diseases smoking
Contraindications for implant placement Immune system defects Infection in maxillary region Sinusitis
Endocarditis Sensitivity to penicillin and its derivatives
Destructive parafunctional habits requiring Advanced Bone Surgery or Ridge Augmentation Pregnancy and lactation Uncontrolled diabetes

Age

From 18 years old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: 30
More than 1 sample in each individual
Number of samples in each individual: 2
Each side of the mouth is considered as a sample.
Actual sample size reached: 15
More than 1 sample in each individual
Actual sample size in each individual: 2
Each side of the mouth is considered as a sample.

Randomization (investigator's opinion)

Randomized

Randomization description

Surgical areas are randomly divided into two groups by www.randomization.com site.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients are unaware of which treatment group they are.
The outcome measurer is different from whom that cures patients.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad university of medical science

Street address

Daneshgah Ave

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Approval date

2019-06-26, 1398/04/05

Ethics committee reference number

IR.MUMS.DENTISTRY.REC.1398.031

Health conditions studied

1

Description of health condition studied

bone deficiency in the posterior maxillary region

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Postoperative pain

Timepoint

2 and 7 days after surgery

Method of measurement

with Visual analogue scale

2

Description

edema

Timepoint

2 and 7 days after surgery

Method of measurement

with Visual analogue scale based on Pasqualini et al. (2005)

3

Description

Duration of surgery

Timepoint

From the beginning of the osteotomy to the end of the bone window preparation

Method of measurement

Stopwatch

Secondary outcomes

empty

Intervention groups

1

Description

Control group: open sinus lift surgery using rotative diamond burs

Category

Treatment - Devices

2

Description

Intervention group: In patients requiring bilateral dental implant placement in the maxilla, one side of the mouth (intervention) will be randomly assigned to create a bone window in the open sinus lift surgery by Piezosurgery device.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Implant department of Babol dental faculty and a private office in Mashhad

Full name of responsible person

Saba Salami

Street address

Daneshgah Ave

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9177948959

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+98 51 1843 3363

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Salamis921@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Reza Shah Akbari

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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

Public

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

Reza Shah Akbari

Position

Associated professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Reza Shah Akbari

Position

Associated professor

Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Saba Salami
Position
dentist
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available