Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 univercity 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 departmet 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
Street address
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shahakbariR@mums.ac.ir
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 professer
Latest degree
Specialist
Other areas of specialty/work
Dentistry
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Person responsible for scientific inquiries

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Person responsible for updating data

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Full name of responsible person
Saba Salami
Position
dentist
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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