Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Aug 2026

Clinical comparison of sinus lift via piezosurgery and usual rotary techniques especially in terms of the pain after surgery in two sides of a single patient, in people who need bilateral sinus lift and implant in posterior sides of maxilla

Protocol summary

Study aim
Clinical comparison of sinus lift surgery via piezosurgery and usual rotary techniques

Design
In order to make a better clinical comparison and eliminate intervening variables such as age and gender, both sinus lift surgery methods are performed for a specific patient with bilateral posterior areas who have no teeth; Therefore, each patient is considered his own control. Randomization was done with Excel software and the sample size is 22 people, also the trial is one_side blinded

Settings and conduct
Patients get the same and standard antibioftic therapies and analgesics and also the same implant system is used on both sides. The corresponding maxillofacial surgeon is a single person and the examinations of the second stage of the surgery are performed by another person, blindly. The surgical method is performed as a lateral_wall approach sinus lift and the minimum vertical height of the bone should be 5mm so that it is possible to place the implant simultaneously with the sinus lift. In the next steps, post-surgery evaluations are done. The place where interventions are done, is also a private office.

Participants/Inclusion and exclusion criteria
Over 18 years old, systematically healthy, Needing bilateral sinus lift and implant for the posterior areas of maxilla; immune system defect, infection in poterior areas of maxilla, sinusitis, needing advanced bone surgery or transverse ridge augmentation, destructive parafunctional habit, pregnant or lactating women.

Intervention groups
Sinus lift surgery, which is examined in this study, is performed by two interventional methods, including piezosurgery and surgery with conventional rotary devices. In this study, both surgical methods are performed on the same person. In fact, each person is considered a control sample for himself and comparison is made.

Main outcome variables
Pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221209056759N1**
Registration date: **2023-01-08, 1401/10/18**
Registration timing: **registered_while_recruiting**

Last update: **2023-01-08, 1401/10/18**
Update count: **0**

Registration date
2023-01-08, 1401/10/18

Registrant information

Name
Hadi Mohammadi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 87 3366 4645

Email address
hadi.mohammadi@muk.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2022-11-02, 1401/08/11

Expected recruitment end date

2023-01-13, 1401/10/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical comparison of sinus lift via piezosurgery and usual rotary techniques especially in terms of the pain after surgery in two sides of a single patient, in people who need bilateral sinus lift and implant in posterior sides of maxilla

Public title

Clinical comparison of sinus lift via piezosurgery and usual rotary techniques

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Over 18 years old Needing bilateral sinus lift and implant for the posterior areas of maxilla Systematically healthy

Exclusion criteria:

Immune system defect Infection in poterior areas of maxilla Sinusitis Needing advanced bone surgery or transverse ridge augmentation Destructive parafunctional habit Pregnant or lactating women

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **22**

More than 1 sample in each individual

Number of samples in each individual: **2**

Right posterior areas of maxilla and left posterior areas of maxilla from a single patient

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization method; It is with quadruple blocks with individual randomization unit. Excel software has also been used for randomization. Concealment has been done in such a way that two independent envelopes are available, one is available to the secretary and the other is available to the surgeon. With each patient's visit, the secretary assigns a row number to the patient based on the order of the visit (after meeting the entry and exit criteria). The surgeon has her own sealed envelope and acts based on it.

Blinding (investigator's opinion)

Single blinded

Blinding description

Before participating in the trial, patients have a complete awareness of reciveing two therapeutic intervention through two surgical methodes; but they do not know that which surgery will be done first and which side (right or left) will get the surgery first.

Placebo

Not used

Assignment

Crossover

Other design features

With the exact design of the study in the form of split-mouth crossover, it is tried to eliminate intervening variables that may have confusing results.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committe of Kurdistan University of medical sciences

Street address

Ethics committe, second floor, medical faculty, Kurdistan medical University, Pasdaran Blvd

City

Sanandaj

Postal code

6617713446

Approval date

2022-11-02, 1401/08/11

Ethics committee reference number

IR.MUK.REC.1401.271

Health conditions studied

1

Description of health condition studied

Sinus lift surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain

Timepoint

24, 48, 72 hours and 1 week after surgery

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description
Sinus perforation
Timepoint
During the surgery
Method of measurement
Surgeon's observation

2

Description
Time of surgery
Timepoint
During surgery
Method of measurement
Minures

3

Description
Field of view of the surgery
Timepoint
During the surgery
Method of measurement
Four point scale

4

Description
Eating and sleeping
Timepoint
During the week after surgery
Method of measurement
Pittsburgh Sleep Quality Index and a valid questionnaire for Eating changes

Intervention groups

1

Description
Intervention group:Augmentin (Amoxicillin + Clavulanic acid) plus Acetaminophen 500 mg, is prescribed for all patients (three times a day or TDS) from one day before surgery until five days after surgery. On the day of surgery, after getting sufficient anesthesia by infiltration and anesthesia of posterior and middle superior alveolar nerves and also greater palatine nerve, patiant is prepared for surgery. 5 minutes before surgery, the patient keeps chlorhexidine mouthwash in his mouth for one minute. The surgical method is performed as a lateral_wall approach sinus lift. A crustal incision is made in the area of the implant along with a vertical freeing incision in the distal of the flap. the mucoperiosteal flap is lifted. After complete reflection of the mucoperiosteal flap, osteotomy is performed in the lateral wall of the sinus using piezosurgery (US_11 LED piezo bone surgery Woodpecker) or rotary at a speed of 2000 rpm.After elevating the sinus membrane, implant is placed at the same time according to the manufacturer's protocol. Also, after evaluating the surgical site, Allogenous frozen-dried corticocancellous bone chips (from Iranian tissue product co. and particle size 1000-2000 micrometers) and absorbable membrane (from Brand Iranian tissue product co., size 20 x 30 mm and thickness 3. to 4. mm) is placed and the area is sutured with four-zero nylon thread.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Personal office
Full name of responsible person
Ideh Talimkhani
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sanandaj University of Medical Sciences
Full name of responsible person
Deputy of research and technology
Street address
Kurdistan Province, Sanandaj City, Pasdaran St., below Quds Hospital, Kurdistan University of Medical Sciences Campus, Deputy of research and Technology
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Research@muk.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Sanandaj 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
Hamedan University of Medical Sciences
Full name of responsible person
Ideh Talimkhani
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Oral and maxillofacial surgery
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Person responsible for updating data

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Latest degree
A Level or less
Other areas of specialty/work
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Province
Isfehan
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8145135386
Phone
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Fax
Email
Fatemepooladvand76@gmail.com

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
information gathered from the patients, is collected in the form of a file called sinus lift study data. All patient information can be provided after de-identification.
When the data will become available and for how long
Access will start from the year 1402.
To whom data/document is available
All people who want to access the data are allowed to do so.
Under which criteria data/document could be used
In order to know the information obtained from the patients, they can use the data. The condition of

accessing the data requires providing the person's purpose of access and research resume.

From where data/document is obtainable

Applicants can request access to the data from Fateme Pooladvand. Email address: fatemepooladvand76@gmail.com They can also contact Dr. Ideh Talim Khani. Email address: ideatalimkhani@yahoo.com

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

First, send their desired request. They must comply with the requested conditions and after conducting the necessary checks, this information will be provided to them. Consider the approximate and maximum time of 2 months.

Comments