Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Radiographic comparison of DFDBA alone and in combination with hyaluronic acid gel in socket preservation: Randomized clinical trial.

Protocol summary

Study aim
Radiographic comparison of the effect of using DFDBA alone and with hyaluronic acid gel in the treatment of socket preservation: A randomized clinical trial

Design
Randomized, clinical trial, triple blinded, 10 patients each have at least two non-molar non-adjacent teeth.

Settings and conduct
Study is conducted at Shiraz Dental School. Initial CBCT is reviewed. The flap is reflected, the tooth is removed by the periotome with minimal damage. In half of the cases, the cavity will filled with DFDBA and others with DFDBA and a 1% hyaluronic acid gel and both are coated with collagen membranes. The flap is repositioned and sutured to cover the membrane. After 4 months, new CBCTs are taken and analyzed for width and height changes. Patients are not aware of the type of treatment they receive. The assignment of patients in each group is done by a third person, the surgeon is not aware of the type of substance that is available to him, and the radiologist is not aware of which groups of data are being studied.

Participants/Inclusion and exclusion criteria
Patients who require tooth extraction other than molar teeth to replace with implant and have CBCT at initial visit. Patients should be at least 18 years of age, have adequate oral hygiene and be able to attend surgical procedures. Exclusion criteria are pregnancy, lactation, medications or diseases that interfere with bone metabolism (Paget), osteoporosis, history of head and neck radiotherapy, uncontrolled diabetes, and smoking. The teeth sockets should have all the walls before extraction and do not have dehiscence more than 3 mm at the time of surgery. Also, adjacent teeth should not be restored with amalgam or metal crown.

Intervention groups
Use of hyaluronic acid gel in socket preservation

Main outcome variables
Height and width of the dental socket before and after the surgery in control and test groups

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190120042431N1**
Registration date: **2019-02-16, 1397/11/27**
Registration timing: **prospective**

Last update: **2019-02-16, 1397/11/27**
Update count: **0**

Registration date
2019-02-16, 1397/11/27

Registrant information

Name
pardis haddadi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 71 3229 3028

Email address
haddadi.p@lums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-02-20, 1397/12/01

Expected recruitment end date
2019-03-11, 1397/12/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Radiographic comparison of DFDBA alone and in combination with hyaluronic acid gel in socket preservation: Randomized clinical trial.

Public title
Hyaluronic acid effect on socket preservation
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients who need tooth extraction other than molar teeth to replace with implant. All patients must be at least 18 years of age. Have proper oral hygiene. Can participate in surgical programs. Have CBCT on first visit.
Exclusion criteria:
Pregnancy Lactation Medications, or diseases that interfered with bone metabolism (Paget), osteoporosis History of head and neck radiotherapy Uncontrolled diabetes Long-term use of NSAIDs Steroid-therapy Smoking.
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **10**
More than 1 sample in each individual
Number of samples in each individual: **2**
non-adjacent non-molar tooth
Randomization (investigator's opinion)
Randomized
Randomization description
simple randomization. This is done by using a random number table. A table row and column are chosen randomly and the point of their intersection will be the beginning of sampling. control group samples are selected by moving the row to the right. The rest of the numbers will be in the test group
Blinding (investigator's opinion)
Triple blinded
Blinding description
The patient, the physician and the data analyst, do not know which tooth is in the test group and which is in the control group.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences
Street address
Vice Chancellor for Research and Technology, 7th floor, central building of the Shiraz Medical School, Zand Blvd., Shiraz, Iran
City
Shiraz
Province
Fars
Postal code
7194696434
Approval date
2017-11-22, 1396/09/01
Ethics committee reference number
IR.SUMS.REC.1396.151

Health conditions studied

1

Description of health condition studied
tooth loss
ICD-10 code
K08.1
ICD-10 code description
Loss of teeth due to accident, extraction or local periodontal disease

Primary outcomes

1

Description
Height and width of the alveolar bone in extracted area
Timepoint
4 months
Method of measurement
Comparing the before and after CBCT image

Secondary outcomes

empty

Intervention groups

1

Description
In each area, the tissue flaps will be reflected to expose bone plates, teeth will be extracted with minimal trauma to the hard and soft tissues. Sockets will be curetted and

washed with normal saline to remove all the soft tissues. In each patient, randomly, one of the extraction sockets will fill with DFDBA powder which is an allograft material, and the other one fill with DFDBA powder plus 1% hyaluronic acid gel. Both sockets will be covered with an absorbable alloderm membrane so that the membrane covers at least 3 mm over the alveolar crest. Flaps will then be replaced and sutured with 3-0 vicryl interrupted and mattress sutures.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Shiraz dental school

Full name of responsible person
Pardis Haddadi

Street address
Faraz aprt., 35th Str., Jomhouri Blvd., Shiraz, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Hooman Khorshidi

Street address
Shiraz dental school, ghasrdasht street

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khorshidih@sums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person
Pardis Haddadi

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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Person responsible for scientific inquiries

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Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

radiographic measurements, Data can be shared after unidentifying people

When the data will become available and for how long

Data access starts 6 months after publishing the results

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

sending request to corresponding researcher

From where data/document is obtainable

Sending request via Email

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

answering as soon as possible

Comments