

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 periosteum with minimal damage. In half of the cases, the cavity will be 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz 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

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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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