Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Acellular dermal matrix loaded with zinc oxide nanoparticles as a new membrane in extraction socket preservation technique: a clinical and CBCT study

Protocol summary

Study aim

The aim of this study is to evaluate the acellular dermal matrix zinc oxide nanoparticle loaded as a novel membrane in socket preservation technique, clinically and radiographically by CBCT.

Design

Randomized clinical trial with control group, parallel, double blind

Settings and conduct

This study is an ۴-month a double blind Randomized Controlled Clinical Trial performing on ۲۲ patients referring to the Periodontology department of Shiraz Dental School, requiring extraction of a single root tooth. Patients are allocated in a ۱:۱ ratio to either using ADM (control group) or ZnO nanoparticle loaded ADM (test group). Bone graft will be used in both groups. Clinical and radiographic (CBCT) measurements will be performed at baseline and after ۴ months.

Participants/Inclusion and exclusion criteria

inclusion criteria: Age ≥ ۱۸ years Adequate restorative space for implant-retained restoration Presence of all ۵ walls of the socket At least ۱۰ mm alveolar bone height without impingement on the maxillary sinus or mandibular canal Presence of one mesial and one distal tooth. Exclusion criteria: Presence of periodontal disease Smoking History of systemic diseases that contraindicate oral surgery Long-term non-steroidal anti-inflammatory drug therapy Bisphosphonate therapy Pregnancy or lactation Absence of vestibular or lingual socket wall

Intervention groups

test group: ZnONPs loaded ADM control group: ADM these membranes will be placed on extraction sockets during surgery

Main outcome variables

Clinical evaluation • Vestibular bone thickness (VBT) • Ridge width (RW) • The heights of the vestibular and lingual crest (HVC-HLC) Radiographic CBCT evaluation: The horizontal ridge width(HW-۱, HW-۳, HW-۵). The thickness of the buccal bone plate is measured only at baseline (BBP-۱, BBP-۳, BBP-۵). The height of the socket walls is calculated at the midbuccal (BH) and midlingual (LH)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211224053505N1**
Registration date: **2022-02-19, 1400/11/30**
Registration timing: **registered_while_recruiting**

Last update: **2022-02-19, 1400/11/30**
Update count: **0**

Registration date

2022-02-19, 1400/11/30

Registrant information

Name

Zahra Rastegar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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zahrarastegar@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-14, 1400/11/25

Expected recruitment end date

2022-07-16, 1401/04/25

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Acellular dermal matrix loaded with zinc oxide nanoparticles as a new membrane in extraction socket preservation technique: a clinical and CBCT study

Public title
Title : Acellular dermal matrix loaded with zinc oxide nanoparticles as a new membrane in extraction socket preservation technique: a clinical and CBCT study
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age ≥ ۱۸ years Adequate restorative space for implant-retained restoration Presence of all ۵ walls of the socket At least ۱۰ mm alveolar bone height without impingement on the maxillary sinus or mandibular canal Presence of one mesial and one distal tooth.
Exclusion criteria:
Presence of periodontal disease smoking History of systemic diseases that contraindicate oral surgery Long-term non-steroidal anti-inflammatory drug therapy Bisphosphonate therapy Pregnancy or lactation Absence of vestibular or lingual socket wall
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **22**
Randomization (investigator's opinion)
Randomized
Randomization description
The allocation in test and control groups will be randomly assigned to each patient by computer-generated random number table. The randomization codes will be stored in password-protected portable computers and enclosed in sequentially numbered, identical, opaque, sealed envelopes. The envelopes will be opened in numerical order after tooth extraction.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study is a double blind randomized clinical trial. Randomization and patient allocation to each group will be done by a third person not involved in the other parts of the research.The resident, involved in the project, will perform the ESP surgeries. All pre- and postoperative clinical assessments will be done by a single, masked examiner who is not the operating surgeon and is blind to the groups. Training and calibration for measuring of CBCT criteria are conducted prior to the study to ensure intra and inter examiner reproducibility of the measured outcomes. Radiolographic data will be measured by a radiologist specialist and the resident. The patients are also blind in relation to the groups.
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
Dental school, Ghasrdasht Street,
City
shiraz
Province
Fars
Postal code
7195615878
Approval date
2021-11-03, 1400/08/12
Ethics committee reference number
IR.SUMS.DENTAL.REC.1400.100

Health conditions studied

1

Description of health condition studied
Extraction Socket preservation
ICD-10 code
K05.6
ICD-10 code description
Periodontal disease, unspecified

Primary outcomes

1

Description
Clinical evaluation: After tooth extraction: 1.Vestibular bone thickness (VBT), is measured with a surgical caliper ۲ mm below the residual alveolar bone margin to the nearest ۰.۵ mm
Timepoint
At the baseline before performing the extraction socket

preservation technique and then after 4 months.

Method of measurement

by caliper and periodontal probe

2

Description

Clinical evaluation: After tooth extraction: Ridge width (RW) is measured at the midfacial level of the buccal bone plate using a surgical caliper ۲ mm from the crest of the ridge to the nearest ۰.۵ mm.

Timepoint

At the baseline before performing the extraction socket preservation technique and then after 4 months.

Method of measurement

by caliper and periodontal probe

3

Description

Clinical evaluation: After tooth extraction: The heights of the vestibular and lingual crest (HVC-HLC) is measured by using a periodontal probe to connect the midfacial CEJs of the adjacent teeth, then measuring the vertical distance from that reference line to the crest of bone on the midfacial and midlingual sides.

Timepoint

At the baseline before performing the extraction socket preservation technique and then after 4 months.

Method of measurement

by caliper and periodontal probe

4

Description

Radiographic evaluation: Linear measurements are made on the CBCT images: The horizontal ridge width is calculated at three horizontal lines (۱ mm, ۳ mm, and ۵ mm apical to the most coronal aspect of the crest) perpendicular to a vertical reference line drawn in the center of the extraction socket and crossing its most apical point at baseline (HW-۱, HW-۳, HW-۵)

Timepoint

At the baseline before performing the extraction socket preservation technique and then after 4 months

Method of measurement

by Cone Beam Computed Tomography (CBCT)

5

Description

Radiographic evaluation: Linear measurements are made on the CBCT images: The thickness of the buccal bone plate is measured only at baseline on the same levels apical to the lingual bone crest (BBP-۱, BBP-۳, BBP-۵)

Timepoint

At the baseline before performing the extraction socket preservation technique and then after 4 months

Method of measurement

by Cone Beam Computed Tomography (CBCT)

6

Description

Radiographic evaluation: Linear measurements are made on the CBCT images: The height of the socket walls is calculated at the midbuccal (BH) and midlingual (LH).

Timepoint

At the baseline before performing the extraction socket preservation technique and then after 4 months

Method of measurement

by Cone Beam Computed Tomography (CBCT)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: test group: ZnO Nano Particles loaded Acellular Dermal Matrix, Human skin specimen will be obtained from abdominal plastic surgeries performed in Department of Plastic Surgery, Shiraz University of Medical Sciences. The tissue samples are kept in phosphate buffer saline (PBS: Sigma Aldrich, USA), while penicillin-streptomycin (Sigma Aldrich, USA) and fungisone (Sigma Aldrich, USA) are also added. The skin samples are cut into pieces using a sterile blade and the remained tissue is kept at -۲۰ºC until use. After ۳ times washing with PBS, subdermal fat tissue and hair are excised, NaCl, Triton X۱۰۰ and EDTA solution are used for removal of epidermis. The washing solution is identical using ۰.۵%Triton X۱۰۰ and ۱۰mMEDTA for ۲ times. The ADM, then is incorporated with Zno nanoparticles ۳%.

Category

Treatment - Surgery

2

Description

Control group: Acellular Dermal Matrix manufactored by Regen company

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz university of medical sciences, Dental school, Periodontology department

Full name of responsible person

Farin Kiany Yazdi

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Dental school, Ghasrdasht Street

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Farin Kiany Yazdi
Position
Associate professor
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