Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluation of the effect of Ora-aid tissue adhesive on post-operative pain after tooth extraction

Protocol summary

Study aim
Evaluation of the effect of Ora-aid tissue adhesive on post-operative pain after tooth extraction
Design
A clinical trial with a control group with randomized parallel groups. on 38 patients. A coin is used for randomization
Settings and conduct
Candidates for extraction of both upper first premolar teeth for orthodontic reasons, who were referred from the orthodontic department of Yazd Dental School to the maxillofacial surgery department. The study is not blind because the patient and the doctor see the type of dressing inside the mouth.
Participants/Inclusion and exclusion criteria
inclusion criteria: All patients referred from the Orthodontics Department to the Oral And Maxillofacial Surgery Department of Shahid Sadoughi Faculty of Dentistry, Yazd, who need extraction of both upper 4th premolar teeth. Exclusion criteria: people with systemic diseases, smoking
Intervention groups
Intervention group: maxillary 4th premolar socket, which was bandaged with ora-aid mucosal adhesive after tooth extraction (made by TBM Korea) Control group: maxillary 4th premolar socket on the opposite side, which was bandaged with sterile gauze after tooth extraction
Main outcome variables
pain

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20230204057322N1**
Registration date: **2023-06-23, 1402/04/02**
Registration timing: **prospective**
Last update: **2023-06-23, 1402/04/02**
Update count: **0**
Registration date
2023-06-23, 1402/04/02

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-07-06, 1402/04/15
Expected recruitment end date
2024-03-15, 1402/12/25
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of Ora-aid tissue adhesive on post-operative pain after tooth extraction

Public title
Evaluation of pain reduction of Ora-aid tissue adhesive
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
all patients who should extract their upper 4s for

orthodontic reasons patients visited by Oral and Maxillofacial surgery (OMFS) Department of dental faculty at Shahid Sadughi University (SSU)

Exclusion criteria:

having underlying systemic disease smoking

Age

From **12 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **38**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Simple randomization with coin toss Randomization unit: left or right side of the mouth Randomization Tool: Coins

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Dental Faculty of Yazd Shahid Sadughi University of Medical Sciences

Street address

Dental Faculty of Shahid Sadughi University, Fajr Blvd, Yazd

City

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Province

Yazd

Postal code

8913814396

Approval date

2022-12-12, 1401/09/21

Ethics committee reference number

IR.SSU.DENTISTRY.REC.1401.058

Health conditions studied

1

Description of health condition studied

Post tooth extraction pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

pain measurement

Timepoint

5-12-24-48 hours after intervention

Method of measurement

visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: in the first session and After extraction, the tooth socket is washed with normal saline and then a mucosal adhesive cut in appropriate size is placed on it (ora-aid mucosal adhesive made by TBM South Korea, including cyanoacrylate polymers and hydroxyethyl cellulose).

Category

Treatment - Drugs

2

Description

Control group: In the second session, after extraction, the tooth socket is washed with normal saline and then dressed with sterile gauze.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Dantal Faculty of Yazd Shahid Sadughi University

Full name of responsible person

Dr Mohsen Barzegar

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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https://web.ssu.ac.ir/page-pajoheshi/fa/21/form/pId515
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yazd 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
Yazd University of Medical Sciences
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Dr Mohsen Barzegar
Position
Associate professor
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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
Yes - There is a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
All data is potentially shareable after de-identifying individuals
When the data will become available and for how long
6 months after publication
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
With the permission of the person in charge of the study
From where data/document is obtainable
Oral and Maxillofacial Surgery Department, Ddetnal Faculty, Shahid Sadughi University
What processes are involved for a request to access data/document
After obtaining the approval of the person in charge of the study, a written request should be given to the research vice-chancellor of the faculty
Comments