

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

Name

Mohammad Amin Yektaie

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4467 1315

Email address

m.am.yektaie@gmail.com

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

Yazd

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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Oral and Maxillofacial Department,Dental Faculty,Dahe Fajr blvd,Yazd

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yds1993@ssu.ac.ir

Web page address

<https://web.ssu.ac.ir/index.aspx?tempname=dandanpezeshki&lang=1&sub=202>

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Yazd University of Medical Sciences

Full name of responsible person

Dr Alireza Moradi

Street address

Dean Offices Of Shahid Sadughi University, Bahonar Sq, Yazd

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Web page address

<https://web.ssu.ac.ir/page-pajoheshi/fa/21/form/pld515>

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

Full name of responsible person

Dr Mohsen Barzegar

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Oral and Maxillofacial Surgery (OMFS)

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Latest degree

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Person responsible for updating data

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Full name of responsible person

Mohammad Amin Yektaie

Position

Resident Of Oral and Maxillofacial Surgery

Latest degree

Medical doctor

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

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, Dental Faculty, Shahid Sadoughi 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