Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of the effect of royal jelly on post extraction socket healing ; A randomized triple blind clinical trial

Protocol summary

Study aim

The aim of this study is to evaluate the topical application of royal jelly on wound healing process of extracted teeth of maxilla and mandible.

Design

Clinical trial with parallel groups, triple blinded and randomized. For randomization Random allocation software will be used. Groups are formed as control of maxilla and mandible, study of maxilla and mandible.

Settings and conduct

The study will be held at oral and maxillofacial surgery section of isfahan university of medical sciences. After tooth extraction and rinsing the socket with sterile normal saline, in control groups gelatamp smeared with sterile normal saline will be applied on the fresh tooth socket. In study groups gelatamp smeared with royal jelly which is freeze dried and diluted to 5% in sterile normal saline will be applied on the fresh tooth socket. In all patients study variables will be evaluated and recorded in study and control groups in two periods (after tooth extraction and 1 week later). Patients, dentist recording variables and statistics analyzer won't be aware of patient's groups.

Participants/Inclusion and exclusion criteria

Patients referred for extraction of not impacted molar teeth in maxilla or mandible, being at least 18 years old and healthy enter the study. In case of pregnancy, using medication or mouthwash, need of antibiotic prophylaxis, allergy to honey, addiction or regional infection patients won't enter the study.

Intervention groups

In control groups gelatamp smeared with sterile normal saline will be applied on the fresh tooth socket. In study groups gelatamp smeard with royal jelly which is freeze dried and diluted to 5% in sterile normal saline will be applied on the fresh tooth socket.

Main outcome variables

The variables of the study include the size of the wound, bleeding after touching, the appearance of pus, the appearance of granulation tissue, the color of the tissue and pain.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221127056634N1**
Registration date: **2023-01-23, 1401/11/03**
Registration timing: **prospective**

Last update: **2023-01-23, 1401/11/03**
Update count: **0**

Registration date

2023-01-23, 1401/11/03

Registrant information

Name

Ali Mazdak

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3267 4556

Email address

alimazdak@res.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-04, 1401/11/15

Expected recruitment end date

2023-04-21, 1402/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of the effect of royal jelly on post extraction socket healing ; A randomized triple blind clinical trial

Public title
Evaluation of the effect of royal jelly on post extraction socket healing

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
All patients who refer for extraction of non-impacted molar teeth At least 18 years old Without any systemic disease

Exclusion criteria:
History of the long-term use of non-steroidal anti-inflammatory drugs or corticosteroids or bisphosphonates or chemotherapy drugs or immunosuppressive drugs The need for antibiotic prophylaxis before tooth extraction Known allergy to honey or its products Continuous use of royal jelly in the last 6 months Severe untreated periodontal disease Being under dental treatment Compulsion to use any type of mouthwash or any type of medicine from the time of tooth extraction until ten days later Smoking Addiction to alcohol, drugs, medicine or a certain substance Acute infection or presence of pus in the tooth area Pregnancy

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **52**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, in order to balance the number of patients assigned to each of the two study groups, the permuted block randomization method is used. Also In order not to reveal the last allocation in each block, the size of the blocks is chosen randomly. For this purpose, random blocks with sizes of 4, 6, or 8 are used. This information is given to the random allocation software and the classification of patients is determined. Since all the patients of this study are not selected at the same time and also in order to observe the blinding process as much as possible, before starting the study, 52 empty files are numbered from 1 to 52 and one file is randomly selected for each patient. Based on the patient's file number and its match with the output of the random allocation software, the patient's group is determined. In order to blindness, the patients will not know about the group in which they are placed.

Blinding (investigator's opinion)
Triple blinded

Blinding description
In order to blindness, the patients will not know about the group (intervention or control) in which they are placed. After tooth extraction by first dentist, the variables are evaluated by second dentist (who has no knowledge of the patient's study group for the purpose of blindness). The statistician who analyzes the results will not know about the patient's study groups.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences

Street address
Faculty of Dentistry, Isfahan University of Medical Sciences, Hezarjerib Ave.

City
Isfahan

Province
Isfehan

Postal code
8174673461

Approval date
2022-11-07, 1401/08/16

Ethics committee reference number
IR.MUI.RESEARCH.REC.1401.239

Health conditions studied

1

Description of health condition studied
Post extraction socket healing

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
wound size of tooth socket

Timepoint
Measurement of wound size at the beginning of the

study (immediately after tooth extraction and washing the socket with normal saline) and seven days later.

Method of measurement

Using a caliper (ae JUYA instruments, Istanbul, Turkey)

2

Description

Bleeding after palpation of the tooth socket

Timepoint

Examination of bleeding after palpation at the beginning of the study (immediately after tooth extraction and washing the socket with normal saline) and seven days later.

Method of measurement

Visually

3

Description

The presence or absence of pus in the tooth socket

Timepoint

At the beginning of the study (immediately after tooth extraction and washing the socket with normal saline) and seven days later.

Method of measurement

Visually

4

Description

Presence or absence of granulation tissue in the tooth socket

Timepoint

At the beginning of the study (immediately after tooth extraction and washing the socket with normal saline) and seven days later.

Method of measurement

Visually

5

Description

Tissue color of the tooth socket

Timepoint

At the beginning of the study (immediately after tooth extraction and washing the socket with normal saline) and seven days later.

Method of measurement

Visually

6

Description

Amount of pain

Timepoint

At the beginning of the study (immediately after tooth extraction and washing the socket with normal saline) and seven days later.

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, after tooth extraction and washing the tooth socket with injectable sterile normal saline, pure royal jelly powder (prepared from the pharmaceutical department of Amin Pharmaceutical Co. Isfahan, Iran) which is sterilized through gamma radiation and will be going through Freeze drying process (the inside water will be removed and it becomes a powder); is mixed to a concentration of five percent in sterile normal saline (Sodium Chloride 0.9% for injection, Iranian Parenteral and Pharmaceutical Co. Tehran, Iran). Then the gelatamp smeared with this mixture will be applied on the tooth socket.

Category

Treatment - Drugs

2

Description

Control group: In this group, after tooth extraction and washing the tooth socket with injectable sterile normal saline, gelatamp smeared with sterile normal saline (Sodium Chloride 0.9% for injection, Iranian Parenteral and Pharmaceutical Co. Tehran, Iran) will be applied on the tooth socket.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Dentistry, Isfahan University of Medical sciences

Full name of responsible person

Ali Mazdak

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr. Gholamreza Asgari
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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
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Ali Mazdak
Position
Student
Latest degree
A Level or less
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Person responsible for updating data

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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
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Some of the data including information about main outcome and study variables after making study cases (patients) not identifiable, will be shared.

When the data will become available and for how long

Beginning of accessibility period is 6 months after publishing the article.

To whom data/document is available

Researchers working in academic and scientific institutes and professionals occupied in pharmaceutics departments of pharmacy companies and they have an approved research plan that has a ethical approval.

Under which criteria data/document could be used

If the research plan is to be carried out in the continuation of the current study or in the completion of this study, it is possible to use the data

From where data/document is obtainable

For getting access to data, requests should be sent to study administrators Ali Mazdak or Peiman Mazaheri to email addresses of alimazdak@res.mui.ac.ir or peimanarman1378@gmail.com .

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

After checking the identity information of requester and the correctness of the mentioned ethical approval code and checking the job or academic position data will be shared.

Comments