

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of effect of Hypericum Perforatum extract on soft tissue healing of tooth extraction socket.

#### Protocol summary

##### Study aim

Determination of the effect of Hypericum Perforatum extract on soft tissue healing of tooth extraction socket.

##### Design

The present study is a non-randomized Double-blind clinical trial phase 3 with parallel groups on 30 patients.

##### Settings and conduct

this study will perform on 18-30 year olds who needed bilateral extraction of maxillary premolars for orthodontic reasons between 2021 jan to jun in private orthodontic offices. They are done. Individuals with inclusion criteria and no exclusion criteria are selected from those who refer to the office and after obtaining informed and written consent, enter the study.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: People 18 to 30 years old who need bilateral maxillary premolars extraction for orthodontic reasons. Exclusion criteria: Pregnancy Breastfeeding Traumatic and surgical extractions History of major systemic diseases and allergies Smoking Alcohol abuse History of taking corticosteroids, contraceptives and antidepressants Need to take antibiotics and NSAIDs after tooth extractions Periodontal disease, infection or any pathology at the area of the teeth indicated for extraction Need more than one carpule to create local anesthesia Who are not willing to participate during the follow ups

##### Intervention groups

Test site: 2ml of biocompatible herbal gel(Hypericum perforatum) will be placed in the postextraction socket and then the socket will be covered with a piece of gauze moistened with normal saline solution. Control site: After a gentle wash with normal saline, the moistened sterile gauze is covered with normal saline.

##### Main outcome variables

Pain intensity; Wound size; Wound healing rate

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210113050025N1**

Registration date: **2021-01-21, 1399/11/02**

Registration timing: **prospective**

Last update: **2021-01-21, 1399/11/02**

Update count: **0**

##### Registration date

2021-01-21, 1399/11/02

##### Registrant information

##### Name

Faranak Shafiee

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 87 3366 8770

##### Email address

faranak.shafiee@muk.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-01-30, 1399/11/11

##### Expected recruitment end date

2021-04-20, 1400/01/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of effect of Hypericum Perforatum extract on soft tissue healing of tooth extraction socket.

#### Public title

Effect of Hypericum Perforatum extract on tissue healing.

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

People 18 to 30 years old bilateral maxillary premolars extraction for orthodontic reasons

##### Exclusion criteria:

Pregnancy Breastfeeding Traumatic and surgical extractions History of systemic diseases and allergies Smoking Alcohol abuse History of taking corticosteroids, contraceptives and antidepressants Need to take antibiotics and NSAIDs after tooth extractions Periodontal disease, infection or any pathology at the area of the tooth indicated for extraction Need more than one carpule to create local anesthesia Who are not willing to participate during the follow ups

#### Age

From **18 years** old to **30 years** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

#### Sample size

Target sample size: **30**

More than 1 sample in each individual

Number of samples in each individual: **2**

Right and left Maxillary premolar postextraction sockets

#### Randomization (investigator's opinion)

Not randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

Participants are not informed in which direction the intervention will take place. The socket one side is randomly selected as the test area and the opposite side as the control. Be. If the selected number is even, the right side is defined as the intervention and the left side as the control, and if it is odd, the left side is defined as the intervention and the right side as the control. The dentist who puts herbal gel in the socket identifies the intervention site with a color code in the checklist. The researcher who examines the tooth socket in follow up sessions evaluate the healing process without knowing the meaning of the code.

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Kurdistan University of medical Sciences

##### Street address

Pasdaran ave , Kurdistan University of medical Sciences

##### City

Sanandaj

##### Province

Kurdistan

##### Postal code

6617713446

#### Approval date

2021-01-11, 1399/10/22

#### Ethics committee reference number

IR.MUK.REC.1399.263

## Health conditions studied

### 1

#### Description of health condition studied

postextraction socket healing

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Healing score

#### Timepoint

Third and seventh day after tooth extraction

#### Method of measurement

Healing index by Landry, Turnbull and Howley

### 2

#### Description

Wound size

#### Timepoint

Extraction day (baseline), third and seventh day after tooth extraction

#### Method of measurement

Castroviejo caliper

## Secondary outcomes

### 1

#### Description

Pain severity

## Timepoint

Extraction day (baseline), third and seventh day after tooth extraction

## Method of measurement

Numeric Pain Rating Scale

## Intervention groups

### 1

#### Description

Intervention group: After achieving adequate anesthesia and tooth extraction the dentist will place 2ml of 5% gel containing Hypericum Perforatum extract with the use of a syringe in the intervention side socket and then he will put a piece of gauze moistened with normal saline solution on it and ask the patient to keep the gauze piece in place for 45 min.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: After rinsing gently with normal saline, a piece of gauze moistened with normal saline solution (NSS) will be placed on the socket wound, and the patient is asked to hold the gauze in place for 45 minutes.

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Farshad Moradi DDS Densitary Clinic

##### Full name of responsible person

Farshad Moradi

##### Street address

In front of the Education Organization, At the beginning of Palestine Street, Azadi Square

##### City

Sanandaj

##### Province

Kurdistan

##### Postal code

6616894581

##### Phone

+98 87 3328 8833

##### Email

faranakshafiee@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Sanandaj University of Medical Sciences

## Full name of responsible person

Afshin Maleki

## Street address

Kurdistan University of medical Sciences, Pasdaran Blvd

## City

Sanandaj

## Province

Kurdistan

## Postal code

6617713446

## Phone

+98 87 3366 4645

## Email

maleki43@yahoo.com

## Grant name

## Grant code / Reference number

IR.MUK.REC.1399.263

## Is the source of funding the same sponsor organization/entity?

Yes

## Title of funding source

Sanandaj 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

Sanandaj University of Medical Sciences

#### Full name of responsible person

Zahra Haghghatpasand Astaneh

#### Position

Dentistry intern

#### Latest degree

A Level or less

#### Other areas of specialty/work

Dentistry

#### Street address

Dentistry faculty, Kurdistan University of medical Sciences, Pasdaran Blvd

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sogand.haqiqat76@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Sanandaj University of Medical Sciences

**Full name of responsible person**

Faranak Shafiee

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Sanandaj University of Medical Sciences

**Full name of responsible person**

Zahra Haghigatpasand Astaneh

**Position**

Dentistry intern

**Latest degree**

A Level or less

**Other areas of specialty/work**

Dentistry

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**Postal code**

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**Phone**

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**Email**

sogand.haqiqat76@gmail.com

**Web page address**

## 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**

Yes - There is a plan to make this available

**Title and more details about the data/document**

All data is from the proposal, raw data and project reports

**When the data will become available and for how long**

Data is available from the legal system six months after publication for two years

**To whom data/document is available**

All persons will be able to access the Kurdistan University of Medical Sciences's request to the Kurdistan University of Medical Sciences.

**Under which criteria data/document could be used**

For legal issues and the need to use data in future studies

**From where data/document is obtainable**

Faranak Shafiei, Zahra Haghigat Pasand, Masoud Moradi

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

After submitting a request to the Kurdistan Research and Technology Dept. of Science and Technology, a call for submission is

**Comments**