

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Afshin Maleki

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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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Faranak Shafiee

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Latest degree

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Other areas of specialty/work

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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