Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 between2021 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)

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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
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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
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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 Haghighatpasand Astaneh
Position
Dentistry intern
Latest degree
A Level or less
Other areas of specialty/work
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Person responsible for scientific inquiries

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Assistant Professor

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Person responsible for updating data

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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