Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effectiveness of Lactuca Sativa in Postoperative Pain Control Following Surgical Removal of Impacted Mandibular Third Molars (Wisdom Tooth): Double Blind Randomized Clinical Trial.

Protocol summary

Study aim
Evaluation of effectiveness of Lactuca sativa in postoperative pain control following surgical removal of impacted mandibular third molars.

Design
Clinical trial with control group, parallel groups, double blind, randomized

Settings and conduct
Effectiveness of Lactuca Sativa after mandibular third molar surgery was evaluated in terms of patient's pain. The split mouth was divided into Lactuca Sativa or placebo syrup. In this double blinded study, patients and researchers were unaware of the outcome of treatment with Lactuca Sativa or placebo. The study was conducted at the faculty of dentistry of Arak University of Medical Sciences. The pain intensity of the patients was evaluated on the first to fourth day after surgery with the VAS scale.

Participants/Inclusion and exclusion criteria
All patients with symmetrical mandibular third molars with full bone or relative bone, in the same classification (in terms of spatial orientation and position of tooth, depth of impaction and relationship with Ramus in radiography) and with same degree of surgical difficulty, painless up to day surgery, without systemic disease, and history of allergy or bleeding problems.

Intervention groups
Intervention group :Use of Lactuca Sativa after mandibular third molar surgery that will be used 3 days before surgery, 3 times a day, and each time a bowl of spoon will be consumed half an hour after the meal, and the same way, until 4 days after surgery It will continue. Control group: Use of placebo syrup after mandibular third molar surgery that will be used 3 days before surgery, 3 times a day, and each time a bowl of spoon will be consumed half an hour after the meal, and the same way, until 4 days after surgery It will continue.

Main outcome variables
Postoperative pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180828040899N2**
Registration date: **2020-07-16, 1399/04/26**
Registration timing: **retrospective**

Last update: **2020-07-16, 1399/04/26**
Update count: **0**

Registration date
2020-07-16, 1399/04/26

Registrant information

Name
Hadi Jafari

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-11-22, 1397/09/01

Expected recruitment end date
2019-01-21, 1397/11/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of Lactuca Sativa in Postoperative Pain Control Following Surgical Removal of Impacted Mandibular Third Molars (Wisdom Tooth): Double Blind Randomized Clinical Trial.

Public title

Effectiveness of Lactuca Sativa in Postoperative Pain Control Following Surgical Removal of Impacted Mandibular Third Molars (Wisdom Tooth).

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients with symmetrical mandibular third molars with full bone or relative bone in the same classification (in terms of spatial orientation and position of tooth, depth of impaction and relationship with Ramus in radiography) with same degree of surgical difficulty require Surgery of Impacted mandibular third molars All patients have good health painless up to day surgery

Exclusion criteria:

Patients with a previous medical history or report of systemic disease history of allergy Smokers Patients with a history of long-term use of antibiotics and corticosteroids Pregnant women

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **35**

Randomization (investigator's opinion)

Randomized

Randomization description

To determine the surgical side of surgery, the number 1 for lettuce syrup and the number 2 for placebo will be considered. There are 70 envelopes of similar appearance that will be in 35 envelopes number 1 and 35 envelopes number 2, envelopes numbered from 1 to 70, and a random number table will be counted for the first surgery that the patient will be blindfolded. He puts on a number, we give the envelope to the patient while the patient does not know the number is 1 or 2 in the envelope.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study is designed double blinded, so that the participants (patients) initially did not know if the Lactuca Sativa was given or the placebo was unaware, as well as the experts reviewing the results of the two interventions for the type of intervention They are unaware of the patient. In order to achieve the goals of blindness in this study, it needs to be explained that the surgeon specializing in evaluating the results from the use of Lactuca Sativa and placebo syrup is different, and the expert assessing the results is completely unaware of the Lactuca Sativa or placebo syrup and it is someone. Which is selected from the outside of the therapeutic system.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

ScienceArak University of Medical Sciences, Basij Square, Sardasht, Khalij Fars Boulevards

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Province

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Postal code

3848153793

Approval date

2020-02-16, 1398/11/27

Ethics committee reference number

IR.ARAKMU.REC.1398.315

Health conditions studied

1

Description of health condition studied

The patient's pain after mandibular third molars extraction surgery following consumption of Lactuca Sativa

ICD-10 code

Z00-Z99

ICD-10 code description

Factors influencing health status and contact with health services

Primary outcomes

1

Description

Pain scale based on VAS scale

Timepoint

From day one to fourth after surgery

Method of measurement

visual analog scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group :Use of Lactuca Sativa after mandibular third molar surgery that will be used 3 days before surgery, 3 times a day, and each time a bowl of spoon will be consumed half an hour after the meal, and the same way, until 4 days after surgery It will continue.
Category
Treatment - Drugs

2

Description
Control group: Use of placebo syrup after mandibular third molar surgery that will be used 3 days before surgery, 3 times a day, and each time a bowl of spoon will be consumed half an hour after the meal, and the same way, until 4 days after surgery It will continue.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Arak Dental School
Full name of responsible person
Research committee of Arak University of Medical Science . Dr. Mohammad Arjmandzadegan
Street address
Between Andisheh 5 and 6 Alleys, Ghadir Blvd., Nabaei town, Sardasht
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Arak 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
Arak University of Medical Sciences
Full name of responsible person
Hadi Jafari
Position
Dentistry student
Latest degree
A Level or less
Other areas of specialty/work
Dentistry
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Position
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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)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
After the publication of this article in a journal if the privacy of patients is not invaded information will be given to the respected center.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available