Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effectiveness of Lactuca sativa in Postoperative Pain Control Following Periodontal Flap Surgery

Protocol summary

Study aim
Evaluation of Effectiveness of Lactuca sativa in postoperative pain control following periodontal flap surgery

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

Settings and conduct
Effectiveness of Lactuca Sativa after periodontal flap surgery was evaluated in terms of patient's pain. 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
Entry requirements: Female patients aged 18-35 years with bilateral periodontal envelopes 5 to 7 mm deep Exit conditions: Patients with a previous medical medical history or a report of systemic diseases, Smokers, Patients with a history of long-term use of antibiotics and corticosteroids, Pregnant women

Intervention groups
Intervention group :Use of Lactuca Sativa after periodontal flap 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 from after periodontal flap 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: **IRCT20180828040899N1**
Registration date: **2019-10-12, 1398/07/20**
Registration timing: **registered_while_recruiting**

Last update: **2019-10-12, 1398/07/20**
Update count: **0**

Registration date
2019-10-12, 1398/07/20

Registrant information

Name
Hadi Jafari

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 86 3425 4409

Email address
hadj2424der@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-09-21, 1398/06/30

Expected recruitment end date
2019-12-21, 1398/09/30

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 Periodontal Flap Surgery

Public title
Effectiveness of Lactuca sativa in Postoperative Pain Control Following Periodontal Flap Surgery

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Contains double-sided periodontal envelopes 5 to 7 mm deep The teeth involved on both sides of the mandible will be similar Women Patients with a mean age of 18 to 35 years

Exclusion criteria:
Patients with a previous medical history or report of systemic disease 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
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **26**
More than 1 sample in each individual
Number of samples in each individual: **2**
Two similar surgeries are performed in one person, one in the right and the other in the left.

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

City
Arak

Province
Markazi

Postal code
3848153793

Approval date
2019-07-28, 1398/05/06

Ethics committee reference number
IR.ARAKMU.REC.1398.122

Health conditions studied

1

Description of health condition studied
The patient's pain after periodontal flap surgery following consumption of lettuce syrup

ICD-10 code

ICD-10 code description

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 periodontal flap 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 periodontal flap 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. Alireza Kamali
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
Arak University of Medical Sciences
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research@arakmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
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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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
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 sections, including data files, protocols, analysis maps and other sections will be published through Arak University of Medical Sciences upon completion of the project
When the data will become available and for how long
From 3 months after completion of plan
To whom data/document is available
All medical universities and their affiliated researchers
Under which criteria data/document could be used
This data is provided to researchers for research use and for similar work
From where data/document is obtainable
Assistant Professor of Design at Arak University of Medical Sciences
What processes are involved for a request to access data/document
Apply by email to the project supervisor, university consent and information from the project manager
Comments