

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effect of Arnica-Rosemary cream on swelling, trismus and pain following impacted mandibular third molar surgery: A triple-blind, clinical trial study

Protocol summary

Study aim

Evaluation of the effect of Arnica-Rosemary cream on swelling, trismus and pain following impacted mandibular third molar surgery

Design

A clinical trial with parallel intervention and control groups, triple-blinded, randomized and is performed on 30 patients using random allocation software.

Settings and conduct

This study is performed in Qazvin Dental School. After surgery, patients use a coded syringe containing arnica-rosemary or placebo, the contents of which the patient, examiner, and statistician are unaware of and is prepared by someone outside the study.

Participants/Inclusion and exclusion criteria

Having panoramic radiographs of appropriate quality and prepared in the last 6 months not having any systemic disease not using drugs, cigarettes, alcohol and drugs (especially corticosteroids) Non-pregnancy and lactation in women Patient willingness and satisfaction to participate in the study Proper patient cooperation

Intervention groups

Patients are divided into two groups, one group receiving rosemary arnica cream and the other group receiving placebo.

Main outcome variables

pain, swelling, trismus

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170502033761N2**

Registration date: **2022-06-18, 1401/03/28**

Registration timing: **prospective**

Last update: **2022-06-18, 1401/03/28**

Update count: **0**

Registration date

2022-06-18, 1401/03/28

Registrant information

Name

mahdieh zarabadipour

Name of organization / entity

Qazvin university of medical science

Country

Iran (Islamic Republic of)

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+98 28 3335 3061

Email address

mzarabadipour@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-23, 1401/05/01

Expected recruitment end date

2022-10-23, 1401/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Arnica-Rosemary cream on swelling, trismus and pain following impacted mandibular third molar surgery: A triple-blind, clinical trial study

Public title

Evaluation of the effect of Arnica-Rosemary cream on swelling, trismus and pain following impacted mandibular

third molar surgery: A triple-blind, clinical trial study

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having a panoramic view radiography with good quality taken in the past 6 months No systemic diseases No use of drugs, cigarettes, alcohol (specially corticosteroids) Non pregnant or lactating women Patient's willingness and satisfaction to participate Proper patient cooperation

Exclusion criteria:

complications during surgery Patient non-cooperation

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

4

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are divided into two groups of intervention and placebo using Random allocation software. Working with this software is such that it provides an order of numbers with a completely random and irregular sequence. The researcher pre-defines how to assign these numbers to study groups and proceeds accordingly.

Blinding (investigator's opinion)

Triple blinded

Blinding description

after surgery patients use a coded syringe containing arnica-rosemary or placebo that the patient, examiner and statistician do not know the contents of and is prepared by a person who is not a participant in the study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Qazvin University of Medical Sciences

Street address

Qazvin university of medical sciences, Bahonar Blvd, Qazvin city

City

qazvin

Province

Qazvin

Postal code

3419915315

Approval date

2020-11-29, 1399/09/09

Ethics committee reference number

IR.QUMS.REC.1399.343

Health conditions studied

1

Description of health condition studied

pain, swelling, truisms

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Patient's Visual Analogue score score

Timepoint

Pain is measured before and immediately after surgery, as well as 3, 7, and 14 days after surgery.

Method of measurement

Pain is assessed by the Visual Anaolgue Score.

2

Description

swelling measurements in millimeter

Timepoint

Swelling is measured before and immediately after surgery, as well as 3, 7, and 14 days after surgery.

Method of measurement

Swelling is measured by constant facial distances with a 4-0 vicryl thread and a millimeter-scale ruler.

3

Description

maximum mouth opening in millimeter

Timepoint

Trismus is measured before and immediately after surgery, as well as 3, 7, and 14 days after surgery.

Method of measurement

Trismus is assessed by a caliper by measuring the maximum distance between the edges of the upper and lower incisor teeth.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Arnica-Rosemary demulcent la farrerr cream Dr. Kamkar International and Research Laboratories Company for two weeks, 2 times a day and each time 1 milliliter.

Category

Treatment - Drugs

2

Description

Control group: Placebo for two weeks, 2 times a day and each time 1 milliliter.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

dental faculty of Qazvin university of medical sciences

Full name of responsible person

Dr. Pejman Janbaz Asiabar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Dr Mahdi Mirhashemi

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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

Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Dr. Pejman Janbaz

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

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Full name of responsible person

Dr. Pejman Janbaz

Position

Assistant Professor

Latest degree

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Person responsible for updating data**Contact****Name of organization / entity**

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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 personal information of study participants and information about the main outcomes will be shared.

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Data available to academic researchers

Under which criteria data/document could be used

There are no other conditions.

From where data/document is obtainable

Qazvin university of medical sciences faculty of dentistry
00982833336001

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

Contact with the research unit of Qazvin University of Medical Sciences

Comments