Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effect of herbal gel containing of Satureja Khuzistanica, Matricaria chamomilla and Syzygium aromaticum On dental pain and comparing with Benzocaine20% topical gel

Protocol summary

Study aim
Comparison of the effect of herbal gel containing Khuzestani savory extract, German chamomile and clove with 20% benzocaine topical gel on toothache

Design
This study is conducted on patients with irreversible pulpitis referring to specialized and general dental clinics in Kashan city. These patients come with toothache and tend to receive medicine that temporarily relieves the pain. Then the patients will be randomized into two treatment groups. The tooth should be flat. A cotton ball is dipped in medicine and placed inside the cavity. The first group was treated with herbal gel made by Barij Essance Company and the second group was treated with 20% benzocaine gel made by Avant Dental Company. The pain intensity questionnaire, which is designed based on the VAS scale, is given to the patient to complete before taking the medicine. The benzocaine used contains 20% benzocaine and is manufactured by Avant Dental. The herbal gel under study contains three plants: clove, Khuzestani sweet and German chamomile, and it is manufactured by Barij Essans Company.

Settings and conduct
Specialized and general dental clinics in Kashan city

Participants/Inclusion and exclusion criteria
• Irreversible pulpitis • Willingness to participate in the study • Quetta's teeth • Patients with a history of systemic diseases

Intervention groups
Herbal gel containing savory extract of Khuzestan, German chamomile and cloves

Main outcome variables
VAS Accompanying symptoms the pain Performance - life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240215061012N1**
Registration date: **2025-02-05, 1403/11/17**
Registration timing: **registered_while_recruiting**

Last update: **2025-02-05, 1403/11/17**
Update count: **0**

Registration date
2025-02-05, 1403/11/17

Registrant information

Name
Kowsar Rahmatpanah

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 5557 5569

Email address
kowsarrahmatpanah77@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-04-20, 1403/02/01

Expected recruitment end date
2025-04-21, 1404/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of herbal gel containing of Satureja Khuzistanica,

Matricaria chamomilla and Syzygium aromaticum On dental pain and comparing with Benzocaine20% topical gel

Public title
Effect of herbal gel containing of Satureja Khuzistanica, Matricaria chamomilla and Syzygium aromaticum On dental pain and comparing with Benzocaine20% topical gel

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Willingness to participate in the study Irreversible pulpitis Cavity tooth
Exclusion criteria:
• Patients with a history of systemic diseases

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization is done by block method (Permuted block randomization) so that first all 4 blocks containing two codes A and B are prepared (6 blocks) and then random blocks are selected by placement using a table of random numbers. These blocks form a sample-sized sequence of A and B codes, each of which is randomly assigned to one of the groups. The list of relevant codes will remain in the formulation department of Barij Essan Company until the design is completed, with this method, both blinding and randomization will be provided.

Blinding (investigator's opinion)
Double blinded

Blinding description
Both gels are prepared in the same packaging, size, shape, and color, and neither the patient nor the doctor will know the nature of the drug until decoding. Also, for statistical analysis, the statistician is unaware of the type of drug and knows two groups with the names A and B. All information about the code of drugs is in the formulation department of Barij-Essan Pharmaceutical Company, and after the completion of the design, the real names of the groups will be determined.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee, Faculty of Medicine and Dentistry, Kashan University of Medical Sciences
Street address
Parastar Blvd, Ghotb Ravandi Blvd
City
Kashan
Province
Isfehan
Postal code
8714844151

Approval date
2023-10-22, 1402/07/30

Ethics committee reference number
IR.KAUMS.MEDNT.REC.1402.175

Health conditions studied

1

Description of health condition studied
Irreversible pulpitis

ICD-10 code
K04.0

ICD-10 code description
Pulpitis

Primary outcomes

1

Description
Patient's pain score based on VAS

Timepoint
The day of visit and the third day after visit

Method of measurement
Visual Analog Scale

2

Description
Improvement based on patient opinion

Timepoint
The day of visit and the third day after visit

Method of measurement
Overall patient assessment

Secondary outcomes

empty

Intervention groups

1

Description
In the first intervention group, patients will receive topical herbal gel. This medicine contains 2% chamomile extract, 1% satureja khuzestanica essential oil, and 4% Syzygium aromaticum essential oil. If the tooth is impacted, a cotton ball is soaked in the medicine and placed inside the cavity. Pain intensity will be measured based on the VAS scale before consumption and 10, 20, and 30 minutes after consumption of the medicine on two consecutive days

Category
Treatment - Drugs

2

Description
In the second intervention group, patients will receive a topical gel containing 20% benzocaine. If the tooth is decayed, a cotton ball will be soaked in the medicine and placed inside the cavity. Pain intensity will be measured based on the VAS criterion before use and 10, 20, and 30 minutes after use of the medicine on two consecutive days.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Clinics in Kashan city

Full name of responsible person
Kowsar Rahmatpanah

Street address
Parastar Blvd

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8713783976

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kashan University of Medical Sciences

Full name of responsible person
Mohammad MahdiDabbagh

Street address
Mashhad Ardahal road

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۱۴۶۴۶۵۳۴۷۱

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crm@barijessence.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Barij Essen Pharmaceutical Company

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact

Name of organization / entity
Kashan University of Medical Sciences

Full name of responsible person
Hossein Akbari

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Biostatistics

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Kashan University of Medical Sciences

Full name of responsible person
Mohammad MahdiDabbagh
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

Contact
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Kashan University of Medical Sciences
Full name of responsible person
Hossein Akbari
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Associate Professor
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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
I don't think publishing it will be of any particular help to researchers.
Study Protocol
Yes - There is 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
Yes - There is 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
Title and more details about the data/document
All data is potentially shareable after de-identifying individuals
When the data will become available and for how long
2025
To whom data/document is available
People who are also engaged in the industry can apply to receive them
Under which criteria data/document could be used
Everyone can use and analyze
From where data/document is obtainable
Kashan University of Medical Sciences Barij Essan Company of Kashan
What processes are involved for a request to access data/document
1 month
Comments