Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of parthenium Tanacetum essential oil on on reducing the number of seizures in children with treatment-resistant epilepsy

Protocol summary

Study aim
The aim of this study is to investigate the effect of parthenium Tanacetum essential oil on the clinical indicators of treatment-resistant epilepsy

Design
Randomized double-blind, controlled clinical trial, parallel, phase 2-3 on 64 patients with resistant to epilepsy (32 patients in each group) using computer randomization method

Settings and conduct
64 patients with treatment-resistant epilepsy aged 2-18 years were included in the study and the questionnaire was filled. They will be monitored for 4 weeks while they continue their anti-epileptic drugs, and the variables of the number of attacks, the variety of attacks, the duration of each attack and the time of its occurrence will be recorded. After the end of four weeks, the patients are randomly and double blindly divided into two groups control and placebo. Both groups are given necklaces of the same shape, the same smell and the same color. And for another four-week period, the patients are monitored and the variables will be reviewed after four weeks. The study will take place at the Mashhad University of Medical Sciences, Mashhad, Iran.

Participants/Inclusion and exclusion criteria
children aged 2-18 years with treatment-resistant epilepsy- Epilepsy is defined in such a way that despite receiving medication, their seizures are not controlled and are resistant to treatment.

Intervention groups
Parthenium Tanacetum plant essential oil will be prepared by the Pharmacological Research Center of Medicinal Plants, small necklaces will be prepared for children, which have a small compartment and a high-density sponge is placed inside it. One drop of essential oil will be poured on the sponge three times a day. The child will be exposed to the smell of essential oil continuously for 24 hours.

Main outcome variables
Improvement of clinical symptoms of epilepsy (number of attacks, variety of attacks, duration of each attack)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190406043175N10**
Registration date: **2024-04-09, 1403/01/21**
Registration timing: **registered_while_recruiting**

Last update: **2024-04-09, 1403/01/21**
Update count: **0**

Registration date
2024-04-09, 1403/01/21

Registrant information

Name
fatemeh forouzanfar

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3761 7318

Email address
forouzanfarf@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-04-02, 1403/01/14

Expected recruitment end date
2026-04-03, 1405/01/14

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of parthenium Tanacetum essential oil on on reducing the number of seizures in children with treatment-resistant epilepsy

Public title

The effect of parthenium Tanacetum on epilepsy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

children aged 2-18 years who refer to the clinic or neurology department of Qaim Hospital and treatment-resistant epilepsy clinic Epilepsy (based on clinical findings and brain scan) is defined in such a way that despite receiving medication, their seizures are not controlled and are resistant to treatment.

Exclusion criteria:

Presence of underlying metabolic disorder Existence of systemic diseases Allergy to chamomile Respiratory sensitivity leading to mouth breathing Non-continuous use of the essential oil used in the research Intensification of convulsions for any reason that requires a change in medication

Age

From **2 years** old to **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

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

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method will be done using online random sequence generators. The blocks will be consisting of four sites filled by letter A or B. The combination of letters A and B will generate six blocks as follow: AABB, ABBA, BBAA, BAAB, ABAB, BABA. A number between 1 to 6 will be selected randomly and the corresponding combination will be used to assign the patients. For example, if the number 3 came up, the block number 3 with the combination of “BAAB”, the assignment of first 4 patients will be assigned. For assignment remaining 60 patients in to 2 groups we will need 14 more blocks which will be selected as previously explained.

Blinding (investigator's opinion)

Double blinded

Blinding description

The blinding of randomized allocation will be done using closed envelopes method. the sequence of the patients will be placed inside a sealed envelope and upon arrival of the patient the envelope will be opened.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Mashhad University of Medical Sciences, Azadi Square, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Approval date

2024-03-08, 1402/12/18

Ethics committee reference number

IR.MUMS.REC.1402.343

Health conditions studied

1

Description of health condition studied

Drug-resistant epilepsy

ICD-10 code

Epilepsy

ICD-10 code description

Episodic and paroxysmal disorders(G40-G47)

Primary outcomes

1

Description

frequency of epilepsy attack

Timepoint

Early intervention, four weeks after the intervention, eight weeks after intervention

Method of measurement

Questionnaire

2

Description

Diversity of epilepsy attack

Timepoint

Early intervention, four weeks after the intervention, eight weeks after intervention

Method of measurement

Questionnaire

3

Description

Duration of epilepsy attack

Timepoint

Early intervention, four weeks after the intervention, eight weeks after intervention

Method of measurement

Questionnaire

4

Description

Time of epileptic attacks

Timepoint

Early intervention, four weeks after the intervention, eight weeks after intervention

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: parthenium Tanacetum plant essential oil will be prepared by the Pharmacological Research Center of Medicinal Plants, and after the preparation of the essential oil, small necklaces will be prepared for children, which have a small compartment of 2 x 1 x 0.5, and a high-density sponge is placed inside it. One drop of essential oil with 100% concentration is poured on the sponge three times a day. The child will be exposed to the smell of essential oil continuously for 24 hours.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinics affiliated to Mashhad University of Medical Sciences

Full name of responsible person

Hassan Rakhshandeh

Street address

Mashhad University of Medical Science, Azadi Square

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Phone

+98 51 3800 2000

Email

rakhshandehh@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

محسن تفقدی

Street address

Deputy of Research and Technology, Ghorashi Building, next to Hoveyzeh Cinema, University Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3841 1538

Email

ramresearch@mums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Hassan Rakhshandeh

Position

Assistant professor

Latest degree

Medical doctor

Other areas of specialty/work
Medical Pharmacy
Street address
Mashhad University of Medical Sciences, Azadi square
City
mashhad
Province
Razavi Khorasan
Postal code
9177948564
Phone
+98 51 3800 2259
Email
rakhshandehh@mums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Hassan Rakhshandeh
Position
Assistant Professor
Latest degree
Medical doctor
Other areas of specialty/work
Medical Pharmacy
Street address
Mashhad University of Medical Sciences, Azadi square
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948564
Phone
+98 51 3800 2259
Email
rakhshandehh@mums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Hassan Rakhshandeh
Position
Assistant Professor
Latest degree
Medical doctor
Other areas of specialty/work
Medical Pharmacy
Street address
Mashhad University of Medical Sciences, Azadi square
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948564
Phone
+98 51 3800 2259
Email
rakhshandehh@mums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available