

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

investigation of Efficacy and safety of topical application of almond violet oil on reducing the fever of febrile 2-7 years old children'

Protocol summary

Summary

Objectives: To determine the efficacy and safety of topical medicinal products (violet almond oil) to reduce fever in children 2 to 7-year-old and to design an intervention pattern for children with fever Design: In a pilot study children 2- year old with 38-40 degree tympanic temperature randomly divide into two groups. drug(violet almond oil topical) group and the placebo(mineral oil) group. Both receive standard drug. method: First, the fever is recorded in both groups. Then 5 drops of almond oil around the belly rubbed. In Group B with 5 drops of mineral oil is done. Fever Check and recorded every half hour. If there is a fever after 1 hour in each of the two groups given 5 mg per kg of acetaminophen. Participants Inclusion criteria: informed consent of parents Lack of medical assistance or other methods of medicinal plants for four hours before the Study no history of skin allergy to herbal medicines Interventions: classic treatment in both groups - local drug(violet- almond oil) and placebo (mineral oil) The main outcome variables: initial result of the decrease in temperature - a second dose of acetaminophen

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017040723722N2**

Registration date: **2017-05-10, 1396/02/20**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-05-10, 1396/02/20

Registrant information

Name

Vahid tafazoli ali

Name of organization / entity

shiraz university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 3234 5145

Email address

stud4469948004@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, shiraz university of medical sciences

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2017-07-23, 1396/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

investigation of Efficacy and safety of topical application of almond violet oil on reducing the fever of febrile 2-7 years old children'

Public title

efficacy of violet oil in fever

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: Parental informed consent to participate in the study; Lack of medical assistance or other methods of medicinal plants for four hours before the start of the study; 2 to 7-year-old patient with a temperature of 40-38 ° C temporal; No history of skin

allergy to herbal medicines (determined by asking history of allergy to any local herbal medicine); No wound in the navel area exclusion criteria: Ear temperature above 40 degrees; History of allergy to herbal medicines (determined by asking history of allergy to any local herbal medicine); The risk of seizures during the study; Cancel parents collaborated on the study; Patients with a history of seizures successive fever; Hypersensitivity to acetaminophen; Get pyretic 4 hours prior to arrival; Need emergency treatment; Being dehydrated patients with severe situation

Age

From **2 years** old to **7 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

randomized numbers table used for randomization

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

shiraz- Imam Hosein square

City

shiraz

Postal code

Approval date

2018-03-13, 1396/12/22

Ethics committee reference number

IR.sums.rec.1395.203

Health conditions studied

1

Description of health condition studied

Other specified fever

ICD-10 code

R50.8

ICD-10 code description

Fever with chills Fever with rigors Persistent fever

Primary outcomes

1

Description

fever degree

Timepoint

every 30 minute after intervention

Method of measurement

tympenic thermometer

Secondary outcomes

1

Description

classic drug dose

Timepoint

one hour

Method of measurement

register shit

Intervention groups

1

Description

acetaminophane syrup 5 mg/kg at first and every hour if fever exist, mineral oil d drops at first and at the end (after 4 hours)

Category

Placebo

2

Description

acetaminophane syrup 5 mg/kg at first and every hour if fever exist, violet-almond oil d drops at first and at the end (after 4 hours)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir oncology hospital

Full name of responsible person

mahdi shahriari

Street address

shiraz-

City

shiraz- Amir oncology hospital- pediatric oncology

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, shiraz university of medical science

Full name of responsible person

mohsen skandari

Street address

shiraz zand blvd

City

shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, shiraz university of medical science

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

shiraz university of medical sciences

Full name of responsible person

vahid tafazoli

Position

Ph.D

Other areas of specialty/work

Street address

shiraz zand blvd 36 alley suit 2856 of Imam Hasan dorm

City

shiraz

Postal code

7135746661

Phone

+7 132352513

Fax

+7 135746661

Email

mihan5511@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

shiraz university of medical sciences

Full name of responsible person

majid nimrooz

Position

Assistant Professor

Other areas of specialty/work

Street address

shiraz Imam hosein square

City

shiraz

Postal code

7135746660

Phone

+7 132083313

Fax

Email

mnimrouzi@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

shiraz university of medical sciences

Full name of responsible person

vahid tafazoli

Position

Ph.d

Other areas of specialty/work

Street address

shiraz zand blvd alley 36 Imam Hasan dorm n.2856

City

shiraz

Postal code

7135746661

Phone

+7 1335243024

Fax

Email

mihan5511@yahoo.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty