

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of abdominal massage with olive oil compared to paraffin on infantile colic symptoms

Protocol summary

Study aim

The effect of abdominal massage with olive oil compared to paraffin on infantile colic symptoms

Design

This study is a clinical trial with placebo, randomized, double-blind, and phase 2-3 on 80 patients. Patients are assigned into 2 groups of 40 by permuted block randomization method.

Settings and conduct

This study will be performed in a pediatrician's office. The diagnosis of infantile colic will be based on the Rome IV criteria. Infants are included in the study with parental consent and are randomly divided into 2 groups of 40 people. Both groups will receive colic EZ drop. In both groups, abdominal massage with oil is performed 3 times a day for 5 minutes. The duration of the intervention is 2 weeks. All mothers are given a list of nutritional instructions. All parents are also asked to complete a checklist prepared by the researcher on a daily basis. The variables will be evaluated and compared on days 0, 7 and 14.

Participants/Inclusion and exclusion criteria

Inclusion criteria: term infants (gestational age more than 37 weeks) at the age of 4 to 12 weeks, birth weight more than 2500 gr; good general condition, breastfeeding. Exclusion criteria: infantile factors: underlying disease, malnutrition, skin lesions in the abdomen, maternal factors: depression and severe stress, smoking, employment at time of study

Intervention groups

Intervention group: Abdominal massage with liquid paraffin 3 times a day. Control group: Abdominal massage with olive oil 3 times a day

Main outcome variables

Average frequency of crying and fussing, duration of crying and fussing, duration of sleep and frequency of defecation in 24 hours, intensity of crying and fussing, ICS score

General information

Reason for update

Remove of the group 1 (control) and group 4 (Oral consumption of Golghand) from the study

Acronym

IRCT registration information

IRCT registration number: **IRCT20200528047585N1**

Registration date: **2020-06-12, 1399/03/23**

Registration timing: **prospective**

Last update: **2021-12-13, 1400/09/22**

Update count: **2**

Registration date

2020-06-12, 1399/03/23

Registrant information

Name

Maryam Mohamadian

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 3502 7789

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-25, 1400/03/04

Expected recruitment end date

2022-03-20, 1400/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of abdominal massage with olive oil compared to paraffin on infantile colic symptoms

Public title

Anointment in treatment of diseases based on traditional Persian medicine and the effect of topical olive oil application on infantile colic symptoms

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

term infants (gestational age more than 37 weeks) birth weight more than 2500 gr good general condition Breastfeeding

Exclusion criteria:

Infantile underlying disease Infant malnutrition Skin lesions in the abdomen Mother's depression and sever stress Smoking by mother Mother's employment at time of study

Age

From **28 days** old to **84 days** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

permuted block randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

By assigning code to each group, put the code in an opaque and closed envelope and likening the drug and placebo container (olive oil and liquid paraffin)

Placebo

Used

Assignment

Other

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

Deputy of Research and Technology, Ghoreishi building, Next to the Hoveyzeh Cinema, Mashhad

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Province

Razavi Khorasan

Postal code

9138813944

Approval date

2020-02-15, 1398/11/26

Ethics committee reference number

IR.MUMS.REC.1398.300

Health conditions studied

1

Description of health condition studied

infantile colic

ICD-10 code

R10.4

ICD-10 code description

Other and unspecified abdominal pain

Primary outcomes

1

Description

The average duration of colic crying and fussing in 24 hours

Timepoint

0, 7 and 14 days

Method of measurement

Filling daily checklists by parents

Secondary outcomes

1

Description

The average frequency of colic crying and fussing in 24 hours

Timepoint

0, 7 and 14 days

Method of measurement

Filling daily checklists by parents

2

Description

The average duration of colic crying and fussing in 24 hours

Timepoint

0, 7 and 14 days

Method of measurement

Filling daily checklists by parents

3

Description

The average duration of sleep in 24 hours

Timepoint

0, 7 and 14 days

Method of measurement

Filling daily checklists by parents

4

Description

The average frequency of defecation in 24 hours

Timepoint

0, 7 and 14 days

Method of measurement

Filling daily checklists by parents

5

Description

ICS score

Timepoint

0 and 14 days

Method of measurement

Completion of Infantile colic scale questionnaire

6

Description

intensity of colic crying and fussing

Timepoint

0 and 14 days

Method of measurement

Visual analog scale

Intervention groups

1

Description

Control group: Abdominal massage with placebo oil (liquid paraffin) 3 times a day and each time 5 minutes, for 14 days

Category

Placebo

2

Description

Intervention group: Abdominal massage with olive oil 3 times a day and each time 5 minutes, for 14 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Ahmad Shah Farhat's office

Full name of responsible person

Maryam Mohammadian Damaski

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Dr. Mohsen Tafaghodi

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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

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

Maryam Mohammadian Damaski

Position

University student

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Malihe Motavasselian

Position

Science Committee member

Latest degree

Ph.D.

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University student

Latest degree

Medical doctor

Other areas of specialty/work

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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

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

The publication program is not specified yet

When the data will become available and for how long

The publication program is not specified yet

To whom data/document is available

The publication program is not specified yet

Under which criteria data/document could be used

The publication program is not specified yet

From where data/document is obtainable

The publication program is not specified yet

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

The publication program is not specified yet

Comments