

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

A comparative study on the effectiveness of three Protecting methods of Swaddling, abdominal and spinal massage on the infantile colic pain

Protocol summary

Summary

This study will be done with aim to compare the effectiveness of three Protecting methods of swaddling, abdominal and spinal massage on the infantile colic pain Referred to Alzahra Hospital in 2017. This study is non blinded clinical trial. The research population includes all infants that will referred to Alzahra hospital in Isfahan. 100 infants will be selected in an available method and randomly assigned to three intervention groups and one control group. At the beginning of the study, the symptoms of symptoms of colic infants will be recorded by parents on the checklist daily. In the first group (swaddling method), the baby sturdy but in a comfortable position will be put in a blanket or linen cloth and the baby's legs will be fixed. Second group (abdominal massage), the infant in resting position receives abdominal massage in circular shape from the end of the chest 15 minutes and 2 times a day for 5 weeks. In the third group (massage of the spine), the infant lays on the abdomen, then the two sides of the spine from the neck to the hips receives massage for 15 minutes and 2 times a day for 5 weeks. The control group will not receive any interventions. At the end of the study, colic pain will be measured in each of the four groups and the groups will be compared. Inclusion criteria: At least 1 week passed from the start of colicky pain; The absence of enterocolitis symptoms of. Exclusion criteria: Performing other interventions or feed the infant with baby milk powder and cow milk during the study

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017102514333N84**

Registration date: **2017-11-19, 1396/08/28**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-11-19, 1396/08/28

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1821 4653

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Esfahan University of Medical Sciences

Expected recruitment start date

2017-11-11, 1396/08/20

Expected recruitment end date

2017-12-21, 1396/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study on the effectiveness of three Protecting methods of Swaddling, abdominal and spinal massage on the infantile colic pain

Public title

The study on the effectiveness of three Protecting on the infantile colic pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: At least 1 week passed from the start of colicky pain; Breastfeeding for auxiliary, use of milk powder based on interviews with mother; Mother with diploma degree or higher; The absence of enterocolitis in infants based on medical records and their biographies; based on his medical records; Lack of infant congenital dislocation of the hip based on medical records; The absence of pyloric stenosis, according to the mother, and according to the diagnosis of neonatal physician; Mothers drug abuse during pregnancy based on interviews with mothers Exclusion criteria: Performing other interventions or feed the infant with baby milk powder and cow milk during the study; If a week before interventions mother's have been trained in another location.

Age

From **14 days** old to **3 months** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Committee Ethics, Esfahan University of Medical Sciences

Street address

Vice Chancellor for Research Affairs, Esfahan University of Medical Sciences, hezarjarib street

City

Esfahan

Postal code

Approval date

2017-07-18, 1396/04/27

Ethics committee reference number

ir.mui.rec.1396.3.434

Health conditions studied

1

Description of health condition studied

Colic in infants

ICD-10 code

R10.4

ICD-10 code description

Other and unspecified abdominal pain

Primary outcomes

1

Description

Colic pain

Timepoint

Daily for 5 weeks

Method of measurement

Children's Pain Rating Scale (FLACC)

Secondary outcomes

empty

Intervention groups

1

Description

The intervention first group (swaddling method), the baby sturdy but in a comfortable position will be put in a blanket or linen cloth and the baby's legs will be fixed.

Category

Other

2

Description

The second intervention group (abdominal massage), the infant in resting position receives abdominal massage in circular shape from the end of the chest 15 minutes and 2 times a day for 5 weeks

Category

Other

3

Description

The intervention third group (massage of the spine), the infant lays on the abdomen, then the two sides of the spine from the neck to the hips receives massage for 15 minutes and 2 times a day for 5 weeks

Category

Other

4

Description

The control group will not receive any interventions

Category

Other

School of Nursing & Midwifery, Esfahan University of Medical Sciences, hezarjarib street

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Nastaran Esmaeilian Dehkordi

Street address

Shahid Keshari Highway, Sofah Boulevard

City

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City

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Postal code

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+98 31 3792 2906

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Ali Mohammadi

Position

Ph.D. in Nursing

Other areas of specialty/work

Street address

Vice Chancellor for Research Affairs, Esfahan University of Medical Sciences, hezarjarib street

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Email

alimohammadi@nm.mui.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Esfahan University of Medical Sciences

Full name of responsible person

Dr. Mahdi Nematbakhsh

Street address

Vice Chancellor for Research Affairs, Esfahan University of Medical Sciences, hezarjarib street

City

Esfahan

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, Esfahan University of Medical Sciences

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

Esfahan University of Medical Sciences

Full name of responsible person

Nastaran Esmaeilian Dehkordi

Position

MA Student of nursing

Other areas of specialty/work

Street 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