Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of a maternal, educational, supportive and care program on sleeping, pain and crying rate due to colic in 1-5 months infants

Protocol summary

Study aim
The effect of educational-supportive program-maternal care, pain and crying rate due to colic pain in infants aged 1-5 months.

Design
In this study, all infants admitted to the Gonabadi hospital Dr. Derafshi clinic who have colic disease that is confirmed by doctor and then justify parental consent will be invited to study. A total of 88 infants with colic were randomly selected and randomly divided into case and control groups

Settings and conduct
In this study, all infants admitted to the GONABADI hospital clinic and doctor Derafshi clinic who have colic and colic disease is confirmed by doctor.

Participants/Inclusion and exclusion criteria
Collic disease must be approved by the physician according to the Wessel standard.

Intervention groups
A care support program will be conducted on interventional colic pain for 3 weeks in the intervention group and compared to the control group.

Main outcome variables
The amount of colic pain, infant crying, the frequency of crying, the duration of infancy and the severity of infant crying.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20171102037187N2**
Registration date: **2018-02-23, 1396/12/04**
Registration timing: **registered_while_recruiting**

Last update: **2018-02-23, 1396/12/04**
Update count: **0**

Registration date
2018-02-23, 1396/12/04

Registrant information

Name
Maryam Khajeh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 5722 1886

Email address
khajehm941@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-01-29, 1396/11/09

Expected recruitment end date
2019-01-12, 1397/10/22

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of a maternal, educational, supportive and care program on sleeping, pain and crying rate due to colic in 1-5 months infants

Public title
The effect of a maternal, educational, supportive and care program on treatment of infantile colic pain

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Have exclusive breastfeeding. Between 1 and 5 months.

The infant has no autoimmune congenital or nutritional problem. At birth, the term of birth is more than 2500 grams. Appropriate weighing of the infant at that age is based on the percentile in the normal range. No skin lesions in breastfeeding and maternity.

Exclusion criteria:

Good poor feeding. Use of chemical drugs such as anti-pneumonia and ... at the time of the intervention. The child has a history of surgery and swelling. Exclusion of exclusive breastfeeding. The child now has an acute illness, such as a cold, etc.

Age

From **30 days** old to **5 months** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **88**

Randomization (investigator's opinion)

Randomized

Randomization description

All referrers who come to the colic during the winter to spring are invited to study using available samples. Examples that appear on odd days are part of the control group. Examples that go on even days are part of the intervention group.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, all participants are informed on the basis of informed consent and are unaware of the allocation of the groups. And the main seeker who seeks to respond to the research hypothesis is unaware of the outcome of the study.

Placebo

Not used

Assignment

Parallel

Other design features

At the start of the intervention and in a briefing session, a case study and one-person-care counseling program will be provided to the case group and a training booklet will be provided.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Medical Ethics Committee

Street address

Faculty of Nursing and Midwifery, Ibn Sina Avenue, Ph.D., Mashhad, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Approval date

2018-01-12, 1396/10/22

Ethics committee reference number

IR.MUMS.REC.1396.345

Health conditions studied

1

Description of health condition studied

infants colic

ICD-10 code

R10.4

ICD-10 code description

R10.4 Other and unspecified abdominal pain. Abdominal tenderness NOS Colic: NOS infantile

Primary outcomes

1

Description

Pain colic in infants

Timepoint

The severity of colic symptoms in infants before and after intervention in each group is calculated on the third and seventh day of treatment, and each group will be compared on the third and the third day of treatment separately from before intervention (due to taking the third day of treatment, the mean of the treatment for the infant and the day Seventh is the end of intervention treatment).

Method of measurement

In both groups, mothers will complete the checklist based on the criteria for pain relief for severity of crying and hours for infant.The questionnaire includes a tool for evaluating colic pain, Visual Analogue Scale.

Secondary outcomes

1

Description

The amount of colic pain, infant crying, the frequency of crying, the duration of infancy and the severity of infant crying.

Timepoint

Weekly (as the basal stage) record the infant's cry and sleep at night. In the second stage (as an intervention stage), mothers will be advised to run an educational-support-care program for a period of 8 days.

Method of measurement

A researcher-made instrument that has four parts: maternal and infant characteristics, and breastfeeding pattern, maternal nutritional instrument, incubation colic assay (the main tool for the dependent variables), Visual Analogue Scale, including the duration of crying and its frequency in 24 Hours is.

Intervention groups

1

Description

In the case of infants who suffer from colic and have their colic approved by the doctor and are among the criteria for entering the study, parents are informed by written consent.

Category

Prevention

2

Description

Control group:In the control group, probiotic drops are prescribed by the doctor, and the doctor will instruct the doctor how to give it to the infant by the researcher. Telling mothers about how to complete the registration (length of crying, infant crying, 24-hour sleep, and lactating sleep), as well as the breastfeeding model, maternal and infant's demographic information, and maternal nutritional information, by the researcher upon entering the study Is taught. For 8 days, complete the checklist based on the criteria for the pain cache for the severity of the cry and the hours for the infant. On the eighth day after the referral to the clinic, the checklist is delivered to the researcher.

Category

Treatment - Drugs

3

Description

Intervention group: In the intervention group, at a briefing session, a tutorial-support-care program for 30 minutes in person and one-to-one and giving a training booklet and giving the drops of probiotics prescribed by the doctor and how to give it to the infant. Telling mothers about how to complete the registration (length of crying, infant crying, 24-hour sleep, and lactating sleep), as well as the breastfeeding model, maternal and infant's demographic information, and maternal nutritional information, by the researcher upon entering the study Will be taught. For 8 days, they will run an educational-support-care program and within these 8 days, mothers will complete their checklist based on the criteria for pain relief for severity of crying and hours for infancy. On the eighth day after the referral to the clinic, the checklist is delivered to the researcher.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Allameh Bhlol Hospital, Gonabadi and derafshi Doctor's office

Full name of responsible person

Maryam khajeh

Street address

Razavi Khorasan, Gonabad, Saadi St., Vahd Blvd, Allameh Bhlol Gonabadi, Research & Treatment Center

City

Gonabad

Province

Razavi Khorasan

Postal code

info@gmu.ac.ir

Phone

+98 51 5723 6833

Fax

+98 51 5723 6160

Email

Bohlool@gmu.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohsen Tappaghdi

Street address

Faculty of Nursing and Midwifery, Ibn Sina Avenue, Ph.D., Mashhad, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Phone

+98 51 3859 1511

Fax

+98 51 3859 7313

Email

khajehm941@mums.ac.ir

Web page address

Grant name

Grant code / Reference number

960998

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

Tahereh Sadeghi

Position

Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Pediatrics

Street address

Faculty of Nursing and Midwifery, Ibn Sina Avenue, Ph.D., Mashhad, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Phone

+98 51 3859 1511

Email

SadeghiT@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Tahereh Sadeghi

Position

Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Pediatrics

Street address

Faculty of Nursing and Midwifery, Ibn Sina Avenue, Ph.D., Mashhad, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Phone

+98 51 3859 1511

Email

SadeghiT@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Tahereh Sadeghi

Position

Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Pediatrics

Street address

Faculty of Nursing and Midwifery, Ibn Sina Avenue, Ph.D., Mashhad, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Phone

+98 51 3859 1511

Email

SadeghiT@mums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not 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

No - There is not 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

Only part of the data, such as the information on the main outcome, can be shared.

When the data will become available and for how long

"Starting the access period from 1397"

To whom data/document is available

It will be available to researchers working in academic and scientific institutions and industry professionals.

Under which criteria data/document could be used

Based on the diagnostic criteria of Wessel, crying healthy infants for more than 3 hours a day, for 3 days a week, and in 3 consecutive weeks, they are called colic of infancy.

From where data/document is obtainable

This study is a clinical trial study with 5% lower weight in the intervention group. Infants whose crying hours dropped between 1-2 hours a day would decrease as more than 2 hours as relative responders as full responders, and those whose crying hours are unaltered as non-response.

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

2 months approval of the design and approval of the Ethics Committee, 3 months of sampling and intervention, writing of the first and third seasons, 1 month of data recording and statistical analysis, 2 months arranging and finalizing the fourth and fifth chapters, typing and replicating, preparing and accepting the article.

Comments