

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The comparison of the effects of massaging and rocking on infantile colic

Protocol summary

Summary

The aim of this study was to compare the effects of massaging and rocking on the treatment of infantile colic. This randomized clinical trial involved 100 infants who were considered colic were randomly assigned to either infant massage (n=50) or rocking groups (n=50), Mothers in both groups trained the infant massage and rocking technique. Mothers were also asked to apply baby oil to prevent any damage to the skin of the infants and were asked to massage their infants for 15-20 minutes once during the day and once at night before sleeping for one week. In the rocking group, mothers were asked to embrace their children and rock them gently when the symptoms of colic appeared for 5-25 minutes. After recording the number, duration and severity of cries and duration of sleep in a checklist within the seven days of intervention and register any side-effects during this period and two groups compared together.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201106054317N5**

Registration date: **2012-08-27, 1391/06/06**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-08-27, 1391/06/06

Registrant information

Name

Fatemeh Nahidi

Name of organization / entity

Shahid Beheshti University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

Phone

+98 982188202512

Email address

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Recruitment status

Recruitment complete

Funding source

The researchers providing facilities and funding source to conduct this study.

Expected recruitment start date

2010-08-23, 1389/06/01

Expected recruitment end date

2011-01-20, 1389/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of the effects of massaging and rocking on infantile colic

Public title

The comparison of the effects of massaging and rocking on infantile colic

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria were infants who had Wessel's factors or diagnosed with colic by the pediatrician; less than 12 weeks of age; with full-term birth; without any known diseases; who had not received any medical treatment for colic; who did not have any proven gastrointestinal diseases; who were not lactose intolerant and allergic to milk; whose mothers had not smoked during pregnancy and severe anxiety and infants who did not have any skin problems or any limitations for receiving massage. The exclusion criteria were using traditional and medical

treatment during the study and failure in conducting the intervention correctly.

Age

To **1 year** 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**

Used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

The International&Virtual Branch of Shahid Beheshti
University of Medical Sciences& Health Services

Street address

No 19, Shahid Abaspoor St, Next to Shahid Hemmat
Bridge, Valiassr Ave,TEHRAN,IRAN

City

Tehran

Postal code

141553693

Approval date

2010-08-15, 1389/05/24

Ethics committee reference number

1769/116

Health conditions studied**1****Description of health condition studied**

Infantile colic

ICD-10 code

R10.4

ICD-10 code description

Other and unspecified abdominal painAbdominal
tenderness NOS

Primary outcomes**1****Description**

Treatment

Timepoint

Daily

Method of measurement

Information form

Secondary outcomes**1****Description**

Side-effect

Timepoint

Daily

Method of measurement

Questionary

Intervention groups**1****Description**

Massage.for 15-20 minutes once during the day and
once at night before sleeping for one week.

Category

Treatment - Other

2**Description**

Rocking :When the symptoms of colic appeared Mothers
embraced their children and rock them gently for 5-25
minutes.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

The pediatric clinic of Amirkabir Hospital of Arak, Iran

Full name of responsible person

Fatemeh Nahidi faculty member of Shaheed Beheshti
University of Medical Sciences ,MSc in Midwifery a

Street address

Arak

City

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Sponsors / Funding sources**1****Sponsor**

Name of organization / entity

Shahid Beheshti University of Medical Sciences&
Health Services

Full name of responsible person

Mohamad Rahmati Roodsari

Street address

No 19, Shahid Abaspoor St, Next to Shahid Hemmat
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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

Shahid Beheshti University of Medical Sciences& Health
Services

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**

The International&Virtual Branch of Shahid Beheshti
University of Medical Sciences& Health Services

Full name of responsible person

Fatemeh Nahidi

Position

Faculty member of Shaheed Beheshti University of
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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Person responsible for scientific

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty