

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of vaccination-related pain in massage therapy, seed therapy and breastfeeding during injection in infants

Protocol summary

Isfahan University of Medical Sciences

Summary

This study is a single blind - randomized clinical trial. 128 infants allocated randomly and systematically in 4 groups (breast feeding, massage, seed and control group). The study population for vaccination HB and DTP in 6 months and MMR in 12 months of all infants who referred to one of the health center in Isfahan. Data gathering was done by questionnaire and checklist (neonatal infant pain scale, NIPS).

Expected recruitment start date

2011-04-13, 1390/01/24

Expected recruitment end date

2011-06-14, 1390/03/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014021815525N2**

Registration date: **2014-08-11, 1393/05/20**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-08-11, 1393/05/20

Registrant information

Name

Mitra Savabi Esfahani

Name of organization / entity

Department of Midwifery, School on Nursing and Midwifery, Isfahan University of Medical science.

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Scientific title

Comparison of vaccination-related pain in massage therapy, seed therapy and breastfeeding during injection in infants

Public title

Comparison of vaccination-related pain in massage therapy, seed therapy and breastfeeding in infants.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: full consciousness infants; taking no medication; lack of any disease; regularly visit infants with Iranian nationality. Exclusion criteria: if he/she was crying and it was impossible to be quiet before injection.

Age

From **1 year** old to **1 year** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **128**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethical Committee of Isfahan University of Medical Sciences

Street address

Hezarjerip Ave, research vice chancellor, Isfahan University of medical sciences, Isfahan

City

Isfahan

Postal code**Approval date**

2011-02-20, 1389/12/01

Ethics committee reference number

390622

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

Pain of vaccines' injection

ICD-10 code

T78.9

ICD-10 code description

Adverse effect, unspecified

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

Pain of vaccine injection

Timepoint

During injection

Method of measurement

Neonatal infant pain scale (NIPS)

Secondary outcomes

empty

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

Intervention group1: breastfeeding

Category

Other

2**Description**

Intervention group 2: massage therapy

Category

Other

3**Description**

Intervention group 3: seed therapy

Category

Other

4**Description**

Group 4: control

Category

Other

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

Navab-Safavi Health Care Center

Full name of responsible person

Sanaz Sheykhi

Street address**City**

Isfahan

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Isfahan University of Medical Sciences

Full name of responsible person

Paiman Adibi

Street address

Hezarjerip Ave, Research vice chancellor, Isfahan

University of Medical Sciences, Isfahan, Iran.

City

Isfahan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Isfahan 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

Isfahan University of Medical Sciences

Full name of responsible person

Mitra Savabi Isfahani

Position

Faculty member, Faculty of Nursing and Midwifery

Other areas of specialty/work

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Contact

Name of organization / entity

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Full name of responsible person

Mitra savabi Esfahani

Position

Academic member, Instructor

Other areas of specialty/work

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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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Zahra Abdeyazdan

Position

Associate Professor

Other areas of specialty/work

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