

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of efficacy of kangaroo mother care, breastfeeding and swaddling on pain score of BCG vaccine in healthy term neonates

Protocol summary

Summary

This research will be done to answer this question that which one of the three non-pharmacological pain management methods (kangaroo mother care, breastfeeding and swaddling), can cause less pain of Bacillus Calmette-Guerin (BCG) vaccine injection. In a clinical trial, 120 healthy term neonates who are to receive BCG vaccine in Shahid Sadoughi Hospital, Yazd, Iran will be randomly distributed into three groups. In group I, breast feeding will be started two minutes before vaccination and continued during and one minute after BCG vaccination. In group II, neonates will receive kangaroo mother care ten minutes before, during and one minute after BCG vaccination and in group III, they will be swaddled ten minutes before, during and one minute after vaccination. In all of them, vaccine will be injected in similar conditions and by a trained person. Primary outcomes include pain score before, during, one minute and two minutes after BCG vaccine injection and obtaining of pain score of less than four during BCG vaccine injection. Pain score will be assessed based on Neonatal/Infant Pain Scale. Secondary outcome will be duration of neonate crying during BCG vaccine injection.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201505142639N16**

Registration date: **2015-06-17, 1394/03/27**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-06-17, 1394/03/27

Registrant information

Name

Razieh Fallah

Name of organization / entity

Shahid Sadoughi University of Medical Sciences, Yazd, Iran

Country

Iran (Islamic Republic of)

Phone

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Email address

fallah@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Research Deputy of Shahid Sadoughi University of Medical Sciences, Yazd, Iran

Expected recruitment start date

2015-04-24, 1394/02/04

Expected recruitment end date

2015-06-25, 1394/04/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy of kangaroo mother care, breastfeeding and swaddling on pain score of BCG vaccine in healthy term neonates

Public title

Efficacy of kangaroo mother care, breastfeeding and swaddling on BCG vaccine pain score in neonates

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria: term neonates (gestation age of 37-42 weeks); birth weight of 2500-4000 g; product of normal

vaginal delivery; without systemic illness and with healthy medical condition Exclusion criteria: birth asphyxia; severe congenital malformation; receiving sedative hypnotic drugs within the past 24 hours

Age

From **1 day** old to **2 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

The trial uses computer generated equal simple randomization by random numbers and data collectors, outcome assessors and data analysts are kept blinded to the allocation.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Sadoughi University of Medical Sciences, Yazd, Iran

Street address

Central building of University, Bahonar square

City

Yazd

Postal code

Approval date

2015-04-22, 1394/02/02

Ethics committee reference number

۱۷/۱/۱۷۷۶۲/پ

Health conditions studied

1

Description of health condition studied

Vaccination

ICD-10 code

Z27

ICD-10 code description

Need for immunization against combinations of infectious diseases

Primary outcomes

1

Description

Pain score of BCG vaccine injection

Timepoint

Before, during, one minute and two minutes after BCG vaccine injection

Method of measurement

Neonatal/Infant Pain Scale

2

Description

Obtaining of pain score of less than four during BCG vaccine injection

Timepoint

During BCG vaccine injection

Method of measurement

Neonatal/Infant Pain Scale

Secondary outcomes

1

Description

Duration of neonate crying during BCG vaccine injection

Timepoint

Every 10 seconds after vaccine injection until stopping of crying

Method of measurement

By chronometer

Intervention groups

1

Description

breast feeding two minutes before vaccination until one minute after BCG vaccination

Category

Prevention

2

Description

kangaroo mother care of neonate with close contact of thorax and abdomen skin of mother ten minutes before vaccination until one minute after BCG vaccination

Category

Prevention

3

Description

swaddling of neonate ten minutes before vaccination until one minute after BCG vaccination

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sadoughi Hospital

Full name of responsible person

Dr. Naeimah Naserzadeh

Street address

Ebn- Sina BIVD, Shahid Ghandi BIVD, Yazd, I.R.Iran

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Deputy of Shahid Sadoughi University of Medical Sciences , Yazd, Iran

Full name of responsible person

Dr. Amirhoshang Mehrparvar

Street address

Central building of University , Bahonar Square

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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

Research Deputy of Shahid Sadoughi University of Medical Sciences , Yazd, Iran

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

Shahid Sadoughi University of Medical Sciences, Yazd, Iran

Full name of responsible person

Dr.Naeimah Naserzadeh

Position

Pediatric resident

Other areas of specialty/work

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Pediatric Ward, Shahid Sadoughi Hospital, Ebn- Sina BIVD, Shahid Ghandi BIVD, Yazd, I.R.Iran

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Position

Pediatric Neurologist , Associate Professor

Other areas of specialty/work

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Position

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Other areas of specialty/work

Street address

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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