

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The study of the effect of breast milk,sugar solution,local anesthesia and Kangaroo mother care (KMC) to heel puncture in pain relief in full term neonates in Marvdasht Motahari hospital(1394)

Protocol summary

Summary

Goal: Study of breast milk, local anesthasia, Dextrose Water 25 % and Kangaroo Mother Care (KMC) in pain management to heel puncture of full term neonates in Marvdasht Shahid Motahari Hospital. Inclusion Criteria: 3-5 days normal fullterm neonate except jaundice. Exclusion Criteria: Formula Milk, NPO, Gestational Diabetic of Mother (GDM) Sampling Size:160 Interventions: Breast milk 15 min before procedure; Kangaroo Mother Care (KMC) 15 min before procedure; Using 2 ml Dextrose Water 25 %, 15min before procedure and local anesthesia (EMLA cream) 15 min bofore procedure. Primary Outcome Measure: Baseline Pain Management.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015120125326N1**
Registration date: **2016-01-24, 1394/11/04**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-01-24, 1394/11/04

Registrant information

Name

Soroush Soltani

Name of organization / entity

Shiraz university of medical sience-International branch

Country

Iran (Islamic Republic of)

Phone

+98 72 8334 5705

Email address

soltaniso@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Science/International Branch

Expected recruitment start date

2015-11-22, 1394/09/01

Expected recruitment end date

2016-01-21, 1394/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The study of the effect of breast milk,sugar solution,local anesthesia and Kangaroo mother care (KMC) to heel puncture in pain relief in full term neonates in Marvdasht Motahari hospital(1394)

Public title

pain management in neonates

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion:Full term neonates. Exclusion:GDM;Infant formula;NPO

Age

From **3 days** old to **5 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **160**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz University of Medical Science, International Branch

Street address

Number 71, Alley 1, Jihad Sazandegi Street, Azadi Square, Shiraz

City

Shiraz

Postal code

7144716699

Approval date

2015-12-13, 1394/09/22

Ethics committee reference number

IR.SUMS.REC.1394.156

Health conditions studied

1

Description of health condition studied

pain management in neonates

ICD-10 code

P59.9

ICD-10 code description

Neonatal jaundice, unspecified

Primary outcomes

1

Description

pain

Timepoint

Baseline

Method of measurement

NIPS

Secondary outcomes

1

Description

Age, Gender

Timepoint

Baseline

Method of measurement

NIPS

Intervention groups

1

Description

Using local anesthesia (EMLA cream) 15 min before procedure

Category

Treatment - Drugs

2

Description

Breast milk 15 min before procedure

Category

Prevention

3

Description

Kangaroo Mother Care 15 min before procedure

Category

Treatment - Drugs

4

Description

Using 2 cc Dextrose Water 25%, 15 min before procedure

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Motahari Hospital

Full name of responsible person

Medical doctor, Soroush Soltani, Intern

Street address

Marvdasht Shahid Motahari Hospital, Shiraz, Fars, Iran

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences
Full name of responsible person
 Doctor Dariyoosh Zohoori
Street address
 Marvdasht Shahid Motahari Hospital
City
 Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 Shiraz University of Medical Sciences
Proportion provided by this source
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

2

Sponsor
Name of organization / entity
 Shiraz University of Medical Sciences
Full name of responsible person
 Soroush Soltani
Street address
 Marvdasht Shahid Motahari Hospital
City
 Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 Shiraz University of Medical Sciences
Proportion provided by this source
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
 Shiraz University of Medical Science, International Branch
Full name of responsible person
 Soroush Soltani

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 Medical doctor, Intern
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Person responsible for updating data

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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