Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparing the pain relief effect of oral 10 percent glucose and expressed breast milk during venous blood sampling among hyperbilirubinemic neonates

Protocol summary

Summary

The aim of this study is to compare the pain relief effect of two methods, namely oral glucose 10 percent and expressed breast milk, in full term neonates during venous blood sampling among hyperbilirubinemic neonates. In this research, the population under study was the full term neonates who were allowed to be fed by mouth. These neonates were needed to be venipunctured, while have not received any sedative and palliative three hours before venipunturing, at least, as well as their mothers. Exclusion criteria for the study includes: regardless of reason it was not possible to do the 2nd venipuncture after the first one. Two sampling processes were constantly and accessibly done on a group of 35 infants, who were chosen randomly, in two days. At the first day the infants were fed breast milk, and on the second day they were fed 10 percent glucose. Each of the investigation on all of the infants have been done in two different days. Both days, infants were fed one milliliters of expressed breast milk or glucose 10 percent two minutes before blood sampling. The pain was measured using neonatal infant scale (NIPS). This instrument measures behavioral indexes of the infant (such as facial expressions, cry and state of arousal, arms and legs movement) and physiological indexes (such as breathing patterns). The measurement outcomes for each infant vary from zero to seven.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201109147557N1**
Registration date: **2013-10-29, 1392/08/07**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-10-29, 1392/08/07

Registrant information

Name

Majid Noroozi Behjat

Name of organization / entity

Kerman University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kerman university of Medical Sciences

Expected recruitment start date

2012-01-21, 1390/11/01

Expected recruitment end date

2012-03-19, 1390/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the pain relief effect of oral 10 percent glucose and expressed breast milk during venous blood sampling among hyperbilirubinemic neonates

Public title

Comparing the pain relief effect of oral 10 percent

glucose and expressed breast milk during venous blood sampling among hyperbilirubinemic neonates

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: 1. Full- term neonates (gestational age 37 to 42 weeks) who needed Venipuncture in order to control the neonatal bilirubin 2. No cotraindication for oral feeding. 3. Tranquilizers and painkillers had not been received at least 3 hours before blood sampling 4. The baby was awake before blood sampling 5. The mother had not received any drugs 6. The infant has not any anomalies, cleft lip and palate. 7. Mother was not diabetic. 8.Infants were fed breast milk of his/her own mother. 9. Clinical signs indicating an increase in bilirubin (according to physician diagnosis). Exclusion criteria for study: 1. neonate discharge before second blood sampling 2.oral feeding contraindication or treatment change during follow up due to an unexpected situation

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: **35**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kerman University of Medical Sciences

Street address

Vice chancellor for research, Kerman University of Medical Sciences, Tahmasebabad Crossroads, Ibn Sina Street, Kerman

City

Kerman

Postal code

Approval date

2010-12-22, 1389/10/01

Ethics committee reference number

467/90/K

Health conditions studied

1

Description of health condition studied

Hyperbilirubinemia

ICD-10 code

P59.8

ICD-10 code description

Neonatal jaundice from other specified causes

Primary outcomes

1

Description

Pain intensity

Timepoint

2 minutes before blood sampling, intervention during 5 minutes, 3 minutes after intervention

Method of measurement

Pain scale measurement NIPS(Neonatale Infant Pain Scale)

Secondary outcomes

empty

Intervention groups

1

Description

expressed breast milk: one ml expressed breast milk once, two minutes before blood sampling.

Category

Prevention

2

Description

glucose 10 percent: one ml glucose 10 percent once, two minutes before blood sampling.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Aliebn Abitaleb(A)

Full name of responsible person

Majid Noroozi Behjat

Street address

Emam Ali Blvd, Rafsanjan

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Rafsanjan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kerman University of Medical Sciences

Full name of responsible person

Dr. Reza Malekpour Afshar

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Vice chancellor for research, Kerman University of Medical Sciences, Tahmasebabad Crossroads, Ibn Sina Street, Kerman

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Kerman

Grant name

91/10/60/2389

Grant code / Reference number

90/467

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Majid Noroozi Behjat

Position

Student of Master degree in Neonatal Intensive Care Nursing

Other areas of specialty/work

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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