

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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 venipuncturing, 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 34 3432 9607

###### Email address

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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

2010-12-22, 1389/10/01

**Ethics committee reference number**  
467/90/K

**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**

**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 (Neonatal 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

**City**

## 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

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

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**

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Nursing**Other areas of specialty/work****Street address**Vice chancellor for research, Kerman University of  
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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**Faculty of nursing and midwifery, Tehran University of  
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Associate professor/Ph.D

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## Person responsible for updating data

#### Contact

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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*