

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison the effect of breastfeeding and oral glucose (10%) on the severity of pain and physiologic characteristics due to venous sampling in infants who Hospitalized in neonatal intensive care unit

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

Comparison the effect of breastfeeding and oral glucose (10%) on the severity of pain and physiologic characteristics due to venous sampling in infants who Hospitalized in neonatal intensive care unit.

Design

Clinical trial with control group, with parallel groups, without blinding

Settings and conduct

The researcher will refer to Seyedoshohada hospital and then the sample according to inclusion criteria will be divided to three homogeneous groups. Intervention will perform once for members of each group . Physiologic responses will be documented 10 min before intervention, during intervention and 10 min after intervention and neonatal pain will be assessed during intervention.

Participants/Inclusion and exclusion criteria

Infants with gestational age more than 30 weeks, Infants without congenital anomalies

Intervention groups

Intervention group 1: they will be embraced the mother and during blood sampling will be eaten breast milk.
Intervention group 2: they will be embraced the mother and during blood sampling will be eaten oral 10% glucose. Control group: they will be embraced the mother without any intervention during blood sampling.

Main outcome variables

Physiological responses, Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190105042245N1**

Registration date: **2019-02-24, 1397/12/05**

Last update: **2019-02-24, 1397/12/05**

Update count: **0**

Registration date

2019-02-24, 1397/12/05

Registrant information

Name

Mojgan Saeidinejad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3247 2508

Email address

m.saednejad@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-20, 1397/12/01

Expected recruitment end date

2019-08-22, 1398/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of breastfeeding and oral glucose (10%) on the severity of pain and physiologic characteristics due to venous sampling in infants who Hospitalized in neonatal intensive care unit

Public title

Comparison the effect of breastfeeding and oral glucose (10%) on the severity of pain and physiologic characteristics due to venous sampling in infants

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Gestational age more than 30 weeks
Lack of congenital anomalies
Lack of mechanical ventilation

Exclusion criteria:

Having nutritional problems
receive sedatives three hours before intervention

Age

From **1 day** old to **28 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **135**

Randomization (investigator's opinion)

Randomized

Randomization description

The sample will be selected from preterm infants according to inclusion criteria. Thus, blocks will be created based on personal information and inside of each block will be divided to three equal parts. Each part is assigned to intervention group 1, intervention group 2 and control group, respectively.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

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

Campus of Kerman medical science university, Haft-Bagh Highway

City

Kerman

Province

Kerman

Postal code

7616913555

Approval date

2018-12-15, 1397/09/24

Ethics committee reference number

IR.KMU.REC.1397.343

Health conditions studied

1

Description of health condition studied

Physiological responses

ICD-10 code

ICD-10 code description

2

Description of health condition studied

pain

ICD-10 code

G89.18

ICD-10 code description

Other acute postprocedural pain

Primary outcomes

1

Description

Arterial oxygen saturation

Timepoint

Before, during and after intervention

Method of measurement

Pulseoximetry

2

Description

Pulse rate

Timepoint

Before, during and after intervention

Method of measurement

Pulseoximetry

3

Description

Pain

Timepoint

During intervention

Method of measurement

NIPS Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: this group will be embraced the mother and they will be eaten breast milk. Physiological

responses will be documented 10 min before intervention, during intervention and 10 min after intervention. Neonatal pain will be checked according to questionnaire.

Category

Other

2

Description

Intervention group 2: this group will be embraced the mother and they will be eaten oral 10% glucose. Physiological responses will be documented 10 min before intervention, during intervention and 10 min after intervention. Neonatal pain will be checked according to questionnaire.

Category

Other

3

Description

Control group: this group will be embraced the mother and will not perform any intervention. Physiological responses will be documented 10 min before intervention, during intervention and 10 min after intervention. Neonatal pain will be checked according to questionnaire.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Seyedoshohada Hospital

Full name of responsible person

Mojgan Saeidinejad

Street address

Seyedoshohada hospital, Esteghlal st.,

City

Kerman

Province

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7617755178

Phone

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Email

beh.host.seyyedshohada@police.ir

Web page address

http://teb.police.ir/hospitals

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Reza Dehnaviyeh

Street address

Kerman medical sciences university, Haft bagh highway

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Phone

+98 34 3132 5402

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Email

rdehnavi@gmail.com

Web page address

http://kmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kerman University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Mojgan Saeidinejad

Position

Nursing MSc student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

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Latest degree

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Relied on secrecy

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available