Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

comparison of analgesic effect of Expressed breast milk (EBM) versus formula and dextrose 50%during venipuncture

Protocol summary

Summary

Objectives: To determine weather expressed breast milk (EBM) is analgesic in healthy term newborns during venipuncture and comparison with formula and 50% dextrose solution. Design: A randomized clinical trial. Setting: Each infant received 3 treatments with EBM, formula and 50% dextrose solution during Venus blood sampling in consecutive 3 days and their responses were measured by behavioral acute pain rating scale for neonates (DAN Score) Participation: A random Sample of 50 full term healthy neonates up t0 14 days who admitted with physiologic icter babies with any medical or congenital conditions such as non pathologic icter , sepsis, asphyxia , major congenital malformations excluded . Main outcome measures: DAN behavioral Scale for neonatal pain were analyzed between EBM groups and central groups during venipuncture . Intervention: Administration of 2 ml EBM, formula and DW50% before 3 consecutive blood sampling in three days .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138808122658N1**
Registration date: **2011-04-06, 1390/01/17**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-04-06, 1390/01/17

Registrant information

Name

Fariba Tarhani

Name of organization / entity

Lorestan Medical University

Country

Iran (Islamic Republic of)

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+98 66 1421 4909

Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Lorestan University of Medical Sciences

Expected recruitment start date

2009-06-22, 1388/04/01

Expected recruitment end date

2010-02-20, 1388/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of analgesic effect of Expressed breast milk (EBM) versus formula and dextrose 50%during venipuncture

Public title

comparison of analgesic effect of Expressed breast milk (EBM) versus formula and dextrose 50%during venipuncture

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: the study population included full term healthy neonate, up to 14 days of post natal age who admitted because of physiologic icter . Exclusion criteria: where babies with any medical or congenital conditions such as non pathological icter , sepsis, asphyxia , major

congenital malformations ,....

Age
From **1 year** old to **14 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Lorestan University of Medical Sciences Ethics committee

Street address
5th km of Boroojerd Road

City
Khorram Abad

Postal code

Approval date
2010-11-02, 1389/08/11

Ethics committee reference number
18661/200

Health conditions studied

1

Description of health condition studied
pain

ICD-10 code
R52.9

ICD-10 code description
Pain, not elsewhere classified

Primary outcomes

1

Description
pain

Timepoint
daily during venipuncture

Method of measurement
DAN score

Secondary outcomes

1

Description
long term effects of painful exprience such as hypersensitivity to painful stimuli

Timepoint
daily during venipuncture

Method of measurement
DAN score

Intervention groups

1

Description
using of Expressed breast milk 2 cc, one dose , daily

Category
Prevention

2

Description
dextrose 50% , one dose , daily

Category
Prevention

3

Description
formula , one dose , daily

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Madani Hospital

Full name of responsible person
Fariba Tarhani MD

Street address
Shaghayegh Square khairabad Street

City
khorramabad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Lorestan University of Medical Sciences Vice Chancellor for research

Full name of responsible person
Fariba Tarhani MD

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5th km of Boroojerd Road, Khorram Abad, Lorestan

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Khorram Abad

Grant name

Grant code / Reference number

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

Title of funding source
Lorestan University of Medical Sciences Vice Chancellor for research

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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Full name of responsible person
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Assistant Professor

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