

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

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

#### Protocol summary

##### Summary

Objectives: To determine whether 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 Venous 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 to 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)

###### Phone

+98 66 1421 4909

###### Email address

tarhani.f@lums.ac.ir

###### 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 experience 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

khorrabad

## 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

**Street address**

5th km of Boroojerd Road, Khorram Abad, Lorestan

**City**

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**

Lorestan University of Medical Sciences

**Full name of responsible person**

Fariba Tarhani MD

**Position**

Assistant Professor

**Other areas of specialty/work**

**Street address**

Shaghayegh Square ,Kheirabad Street

**City**

Khorram Abad

**Postal code**

**Phone**

+98 66 1421 9124

**Fax**

+98 66 1420 0106

**Email**

f\_tarhani44@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Lorestan University of Medical Sciences

**Full name of responsible person**

Friba Tarhani MD

**Position**

Assistant Professor

**Other areas of specialty/work**

**Street address**

Shaghayegh square , Kheirabad street

**City**

Khorram Abad

**Postal code**

**Phone**

+98 66 1421 9124

**Fax**

+98 66 1420 0106

**Email**

f\_tarhani44@yahoo.com

**Web page address**

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Lorestan University of Medical Sciences

**Full name of responsible person**

Shabnam Dalvand

**Position**

Nutritionist

**Other areas of specialty/work**

**Street address**

Shaghayegh square , Kheirabad street

**City**

Khorram Abad

**Postal code**

**Phone**

+98 66 1421 9124

**Fax**

+98 66 1420 0106

**Email**

shabnamdalvand@yahoo.com

**Web page address**

## 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*