

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Comparison The effect of oral sucrose 20%, 30% and 50% on relief of behavioural pain responses caused by vitamin k injection in full term infants

Protocol summary

Semnan University of Medical Sciences

Summary

We will compare the analgesic effect of sucrose 20%, 30% and 50% in 120 healthy term newborns that receive intramuscular vitamin k. The babies will randomly be divided into the 4 groups. Each group will receive 1ml of oral sucrose 20%, 30% or 50% or sterile water. Response to pain will assess by Neonatal Infant Pain Scale (NIPS) immediately after injection and 5 minutes after.

Expected recruitment start date

2010-08-24, 1389/06/02

Expected recruitment end date

2011-08-24, 1390/06/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138902223920N1**

Registration date: **2010-06-16, 1389/03/26**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2010-06-16, 1389/03/26

Registrant information

Name

Fatemeh Morady

Name of organization / entity

Semnan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 23 1444 6529

Email address

morady-f@sem-ums.ac.ir

Recruitment status

Recruitment complete

Funding source

Scientific title

Comparison The effect of oral sucrose 20%, 30% and 50% on relief of behavioural pain responses caused by vitamin k injection in full term infants

Public title

The effectiveness of sucrose in neonatal pain relief

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: gestational age 37-42 weeks, weight above 2/5 kg, age 1-2 day, Apgar (first min) ≥ 7 .

Exclusion criteria: crying, illness, using Naloxan

Age

From **1 year** old to **2 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **120**

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**

Semnan University of Medical Sciences

Street address

Amir Kabir Av.

City

Semnan

Postal code**Approval date**

2010-05-15, 1389/02/25

Ethics committee reference number

2337/2/21

Health conditions studied**1****Description of health condition studied**

Pain caused by vitamin k IM injection

ICD-10 code

Z76.2

ICD-10 code description

Health supervision and care of other healthy infant and child

Primary outcomes**1****Description**

Pain

Timepoint

Immediately after injection and 5 minutes later

Method of measurement

Neonatal Infant Pain Scale (NIPS)

Secondary outcomes

empty

Intervention groups**1****Description**

Sucrose 20%, 1cc oral

Category

Other

2**Description**

Sucrose 30%, 1cc oral

Category

Other

3**Description**

Sucrose 50%, 1cc oral

Category

Other

4**Description**

Sterile Water, 1cc oral

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Amiralmomenin Hospital

Full name of responsible person**Street address****City**

Semnan

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Semnan University of Medical Sciences

Full name of responsible person

Dr Ghorbani

Street address

Semnan, Amir Kabir Av.

City

Semnan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Semnan 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
Semnan University of Medical Sciences
Full name of responsible person
Fatemeh Morady
Position
Master Science of Nursing
Other areas of specialty/work
Street address
Semnan, Dehkoda Av., Miaade 5 St.
City
Semnan
Postal code
Phone
+98 23 1444 6529
Fax
Email
fatemeh_mrdy@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Fatemeh Morady
Position
Master Sciences of Nursing
Other areas of specialty/work
Street address
Semnan, Dehkoda Av., Miaade 5 St.

City
Semnan
Postal code
Phone
+98 23 1444 6529
Fax
Email
fatemeh_mrdy@yahoo.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Full name of responsible person
Fatemeh Morady
Position
Other areas of specialty/work
Street address
City
Postal code
Phone
Fax
Email
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