Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Jun 2026

Comparison of the effect of familiar olfactory stimulation (lavender scent) and glucose on pain from blood sampling in term neonates

Protocol summary

Summary

This study investigated the comparison of the effect of familiar olfactory stimulation (lavender scent) and glucose on pain from blood sampling in term neonates. This was a clinical trial study that carried out on 120 term neonate 3- 13 days that was allocated to three groups (each 40 neonates). In the first group, infants at night for 8 hours before blood sampling were exposed to the scent of lavender. And the next day, at the time of blood sampling was used of the scent of lavender. In the second group, infants 2 minutes before the taking blood sample received 2 cc edible glucose 30% and in the third group, without receipt specific intervention, blood samples were taken. Simultaneously with the needle, Douleur Aigue Nouveau-ne (DAN) scale by a trained person was calculated and recorded. Duration of crying in seconds from start cry to silence that lasted at least 5 seconds interval was measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015010220529N1**
Registration date: **2015-02-16, 1393/11/27**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-02-16, 1393/11/27

Registrant information

Name

Naghmeh Razaghi

Name of organization / entity

Mashhad University of Medical Science

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mashhad University of Medical Sciences

Expected recruitment start date

2012-03-19, 1390/12/29

Expected recruitment end date

2013-03-20, 1391/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of familiar olfactory stimulation (lavender scent) and glucose on pain from blood sampling in term neonates

Public title

The effect of scent and glucose on pain of neonates

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: a- Gestational age over 37 weeks, b- Appearance, Pulse, Grimace, Activity, Respiration (APGAR) scores at five minutes greater than seven c- Non-use of tranquilizer or sedative and anticonvulsant drug during the last 24 hours by mother and neonate d- Need for venous blood sampling e- Stability in general and clinical status f- Oral feeding is not prohibited g- The mother has not received any opioid i- Lack of Diabetes in the mother. Exclusion criteria: a- If the baby in the

familiar scent group, should be taken blood sampling during the orientation phase. b- If the infants in the familiar scent group, during the familiar within scent up to blood sampling, was discharged or to cause any complications or problems that interfere with the natural trend of neonatal care, orientation phase stop. c- If the infant receive milk or any sugar within thirty minutes prior to the start of the blood sampling. d- If the infant is restless and uneasy before blood sampling. e- If the first attempt for blood sampling was not successful.

Age
From **3 days** old to **13 days** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Neonates (N = 120) were randomly assigned to three groups: aromatherapy (n = 40), glucose (n=40) and control group (n = 40). Method of sampling infants in this study is convenient sampling. Because it was probable for the other two groups to be exposed to the lavender scent spread from aromatherapy group (diffusion effect), sampling was done only for one group during each week, with groups being randomly selected; in other words, on the first day, the name of each group was written on a separate piece of paper, then was lottery. During each week, eligible cases were recognized and selected by convenience sampling only for one group, and groups were replaced respectively. Blinding was performed in a manner that the person who Implemented the pain scale was unaware of the purposes of research and study groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences

Street address
Daneshgah Ave,Ghorashi building

City
Mashhad

Postal code

Approval date
2010-12-11, 1389/09/20

Ethics committee reference number
88474

Health conditions studied

1

Description of health condition studied
pain

ICD-10 code
R52

ICD-10 code description
pain not referable to any one organ or body region

Primary outcomes

1

Description
Pain

Timepoint
Immediately after the entry of the needle into the vein

Method of measurement
Pain assessment scale scores Douleur Aigue Nouveau-ne (DAN).The scale is used to evaluate 3 items: facial expressions, limb movements and vocal expression

Secondary outcomes

1

Description
The duration of crying

Timepoint
According to seconds, in 3 minutes at the beginning of the blood sampling was measured.

Method of measurement
Stopwatch

Intervention groups

1

Description
Without receipt specific intervention for pain, blood samples were taken.

Category
N/A

2

Description
Infants at night for 8 hours before blood sampling were exposed to the scent of lavender. And the next day, at the time of blood sampling was used of the scent of lavender.

Category
Treatment - Other

3

Description
Infants 2 minutes before the taking blood sample received 2 cc edible glucose 30%
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Hashemi Nezhad Hospital
Full name of responsible person
Street address
City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Mashhad University of Medical Sciences
Full name of responsible person
Dr. Ramezani
Street address
Daneshgah Ave,Ghorashi building,Research Administration
City
Mashhad
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Mashhad 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

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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