Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Jun 2026

Effect of familiar olfactory stimulation on responses to pain of blood sampling in neonates

Protocol summary

Summary

The purpose of this study is to assess the effectiveness of olfactory stimuli (familiar and unfamiliar) on physiologic and behavioral responses to the pain during arterial puncture in term neonates. In this clinical trial, 135 term neonates of 1 to 7 days of age will be allocated to one of the following groups. During the procedure, familiar odor group will be presented with the vanilla smell. They will be familiarized with prior to the procedure for 9 hours. Unfamiliar odor group will be presented with the vanilla smell, they will not be previously exposed to, and control group will be neither familiarized nor exposed to the odor. The heart rate and O2 saturation levels will be measured before, after inserting and removing the needle. Also crying duration will be measured from the onset until a crying free interval of longer than five seconds.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201011135163N1**
Registration date: **2010-12-01, 1389/09/10**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-12-01, 1389/09/10

Registrant information

Name

Akram sadat Sadat hoseini

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2009-04-10, 1388/01/21

Expected recruitment end date

2009-10-01, 1388/07/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of familiar olfactory stimulation on responses to pain of blood sampling in neonates

Public title

Effect of familiar olfactory stimulation on responses to pain of blood sampling in neonates

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Age 1-7 days, 37-42 weeks of gestational age at birth, no neurologic, cardiologic or respiratory impairments or congenital anomalies
Exclusion criteria: restlessness before the procedure, receiving sedatives or analgesics for 24 hours before the procedure, neonates in whom, the first needling for blood sampling was not successful

Age

To **1 year** 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
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tehran University of Medical Sciences
Street address
Tehran University of Medical Sciences, Keshavarz Boulevard, Tehran
City
Tehran
Postal code
1473656169
Approval date
2008-05-18, 1387/02/29
Ethics committee reference number
87-02-28-7170

Health conditions studied

1

Description of health condition studied
Neonatal pain
ICD-10 code
R52.0
ICD-10 code description
Acute pain

Primary outcomes

1

Description
O2 Saturation
Timepoint
two minutes prior to sampling, after inserting and removing the needle
Method of measurement
pulse oximeter

2

Description
Heart Rate
Timepoint
two minutes prior to sampling, after inserting and removing the needle
Method of measurement
Pulse oximeter

Secondary outcomes

1

Description
Crying duration
Timepoint
from onset until a crying free interval of more than five seconds
Method of measurement
voice recording

Intervention groups

1

Description
For the familiar odor group, familiarization will be performed the night before blood sampling and neonates will be exposed to the vanillin odor during the painful procedure. In this group, a sterile gauze pad (10 × 10 cm) moistened with ten drops of solution of vanillin 0/64% will be placed in the incubator which will be approximately 10 cm from the neonate's head. The next morning, the odorized gauze will be removed with average familiarization duration of 9 hours.
Category
Prevention

2

Description
For neonates in the unfamiliar group, the familiarization will not be carried out but blood sampling will be done in the presence of the vanillin odor 0/64%.
Category
Prevention

3

Description
Control group: no intervention
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
neonatology ward of the Bahrami Children Hospital affiliated to Tehran University of Medical Science
Full name of responsible person
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Fatemeh Rahimikian
Street address
Faculty of Nursing and Midwifery, Tehran University of Medical Sciences, Nosrat St., Tohid Sq., Tehran
City
Tehran
Grant name
پژوهشی
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Akram sadat Sadat Hoseini
Position
Member of faculty- MSc
Other areas of specialty/work
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Web page address

Person responsible for updating data

Contact

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