Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparative Investigating the effect of breast milk odor and rosa damascena essential oil on pain and duration of crying due to blood sampling in neonates

Protocol summary

Study aim
Comparison the effect of breast milk and rosa damascena essential oil odor on pain and duration of crying due to blood sampling in neonates

Design
Cross over clinical trial, phase 2-3 with 40 neonates

Settings and conduct
In this research, the study population are neonates with a fetal age more than 32 weeks admitted to the NICU of Ali Ibn Abitaleb Hospital. Neonates will be select by convenience sampling method based on inclusion criteria. In the first stage, the neonate will expose to a cotton ball soaked in 2 cc of breast milk at a distance of 3 cm from the nose 3 minutes before the blood sampling until the end. In the next step, a cotton ball soaked in 2 drops of 10% rose essential oil will used similar to the breast milk method. For second sample, rose essential oil will used first time and then breast milk in the second time and so on until the end.

Participants/Inclusion and exclusion criteria
Fetal age between 32-42 weeks, neonatal age between 1-10 days, 5-minute Apgar scores higher than 7, parental inform consent for participate, stability of clinical status, newborn awake state and one hour after breastfeeding are inclusion criteria. Hypoglycemia, intubation, congenital or chromosomal abnormalities, painful procedure such as suctioning or blood sampling before the intervention, receiving sedative 24 hours before the intervention, crying and feeding with formula are exclusion criteria.

Intervention groups
Group A: the neonate will expose to a cotton ball soaked in 2 cc of breast milk at a distance of 3 cm from the nose 3 minutes before the blood sampling until the end. In the next step, the need for blood sampling in this neonate, a cotton ball soaked in 2 drops of 10% rose essential oil will used similar to the breast milk method. Group B: rose essential oil will used first time and then breast milk in the second time.

Main outcome variables
Score of pain؛ Duration of crying

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150713023190N11**
Registration date: **2021-11-29, 1400/09/08**
Registration timing: **registered_while_recruiting**

Last update: **2021-11-29, 1400/09/08**
Update count: **0**

Registration date
2021-11-29, 1400/09/08

Registrant information

Name
Tabandeh Sadeghi

Name of organization / entity
Rafsanjan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-10-23, 1400/08/01

Expected recruitment end date
2022-04-21, 1401/02/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative Investigating the effect of breast milk odor and rosa damascena essential oil on pain and duration of crying due to blood sampling in neonates

Public title
Comparison the effect of breast milk odor and rosa damascena essential oil on pain and duration of crying due to blood sampling in neonates
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Fetal age between 32-42 weeks Neonatal age between 1-10 days 5-minute Apgar scores higher than 7 Parental inform consent for participate of their neonate in the study Stability of clinical status Newborn awake state One hour after breastfeeding
Exclusion criteria:
Hypoglycemia Intubation Congenital or chromosomal abnormalities Painful procedure such as suctioning or blood sampling before the intervention Receiving sedative 24 hours before the intervention crying Feeding with formula
Age
From **1 day** old to **10 days** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Rafsanjan University of Medical Sciences
Street address
Imam Ali Blvd
City
Rafsanjan
Province
Kerman
Postal code
7717933777
Approval date
2021-10-02, 1400/07/10
Ethics committee reference number
IR.RUMS.REC.1400.138

Health conditions studied

1

Description of health condition studied
Pain
ICD-10 code
G89.1
ICD-10 code description
Acute pain, not elsewhere classified

2

Description of health condition studied
Duration of crying
ICD-10 code
R68.11
ICD-10 code description
Excessive crying of infant (baby)

Primary outcomes

1

Description
Mean score of pain
Timepoint
Before and after the each of intervention
Method of measurement
Neonatal Infant Pain Scale (NIPS)

2

Description
Duration of crying
Timepoint
Before and after the each of intervention
Method of measurement
Chronometer

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group A: the neonate will expose to a cotton ball soaked in 2 cc of breast milk at a distance of 3 cm from the nose 3 minutes before the blood sampling until the end. In the next step, the need for blood sampling in this neonate, a cotton ball soaked in 2 drops of 10% rose essential oil will used similar to the breast milk method.
Category
Prevention

2

Description
Intervention group B: in this group, rose essential oil will used first time and then breast milk in the second time:
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Ali Ibn Abitaleb Hospital
Full name of responsible person
Ali Mousavi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Rafsanjan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Rafsanjan University of Medical Sciences
Full name of responsible person
Zeynab Heidari
Position
Nurse
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Confidentiality of data
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable