

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 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

Country

Iran (Islamic Republic of)

Phone

+98 34 3425 5900

Email address

t.sadeghi@rums.ac.ir

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

AgeFrom **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

Street address

Mofateh Blvd

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7717933777

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+98 34 3428 0001

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aliebn@rums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Ali Shamsizadeh

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vcrt@rums.ac.ir

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

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Tabandeh Sadeghi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data**Contact****Name of organization / entity**

Rafsanjan University of Medical Sciences

Full name of responsible person

Tabandeh Sadeghi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

parastar Ave

City**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