Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of aromatherapy with Rosa damascena on pain during airway suctioning of infants admitted to neonatal intensive care

Protocol summary

Study aim
Determining the effect of Rosa damascena on pain during airway suctioning in newborns.

Design
A clinical trial with a single-blind control group-on 62 infants-randomization using 62 cards in an envelope based on a numbering table

Settings and conduct
Sixty-two neonates hospitalized in the neonatal intensive care unit of Shahid Sadoughi Hospital in Yazd, if they are eligible, will be enrolled in the study and will be randomly assigned to the intervention or control groups. During suction, the babies are filmed with a mobile phone The pain score is evaluated based on the pain criterion in the newborns in both groups before, during, and after the suction based on the video taken by the research colleague who does not know about the groups

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1-20-day-old infants who were born with a gestational age of 27-36 weeks and are under respiratory support with CPAP nasopharyngeal tube. Exclusion criteria: Infants with anomalies and diseases at birth, infants who do not have stable vital signs.

Intervention groups
Intervention group: Infants in this group received aromatherapy from 3 minutes before until 2 minutes after completion of suction, using 2 drops of 10% rose essential oil (produced by Ide Daru Pars company), poured onto a cotton pad and placed 3 cm away from the infant 's nose. (For desensitization, these infants were exposed to one drop of 10% essential oil 30 minutes before the main intervention.) Control group: Infants were exposed 2 drops of sterile distilled water from a 5 ml vial (produced by Shahid Ghazi Pharmaceutical Company), poured onto a cotton pad and placed 3 cm away from the infant 's nose, from 3 minutes before until 2 minutes after the completion of suctioning.

Main outcome variables
Suction pain

General information

Reason for update

Acronym
ندارد

IRCT registration information
IRCT registration number: **IRCT20241029063534N1**
Registration date: **2025-03-20, 1403/12/30**
Registration timing: **prospective**

Last update: **2025-03-20, 1403/12/30**
Update count: **0**

Registration date
2025-03-20, 1403/12/30

Registrant information

Name
Saide Karamshahi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 34 4334 0115

Email address
saeedekararmshahi@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-03-21, 1404/01/01

Expected recruitment end date
2025-07-23, 1404/05/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of aromatherapy with Rosa damascena on pain during airway suctioning of infants admitted to neonatal intensive care

Public title
Investigating the effect of the smell of Rosa damascena on suction pain in infants

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
mother's consent for the newborn to participate in the research Newborns on respiratory support with a non-invasive method with a nasopharyngeal tube (NCPAP) with a gestational age of 27 to 37 weeks Confirmation of the absence of olfactory problems in the newborn by a specialist doctor no systemic disease or early anomalies. Having an Apgar score higher than and equal to 7 at the time of birth, Birth weight above 1000 grams The baby being calm and awake Not taking acetaminophen or any other painkillers. 4 hours before the suction procedure The temperature is between 36 and 37.5 The absence of hypoglycemia The absence of previous painful interventions such as circumcision, vein ligation

Exclusion criteria:
Infants with congenital anomalies and diseases Infants who do not have stable vital signs

Age
From **1 day** old to **28 days** old

Gender
Both

Phase
3

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **62**

Randomization (investigator's opinion)
Randomized

Randomization description
Eligible infants will be selected and then through a simple random method divided into two equal groups. A table of numbers from 1 to 62 will be prepared, with the intervention group labeled as A and the control group as C .Thirty one papers marked with the letter A and thirty one papers marked with the letter C will be placed in an envelope. For each number in the table, one paper will be drawn from the envelop until the last number is reached. This process ensures randomization.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, each infant will be assigned to one of two groups (intervention or control) based on a randomization table. During the suctioning process a video will be recorded of the infant using a Samsung mobile phone. The pain score is evaluated based on the pain criterion in the newborns in both groups before, during, and 2 minutes after the suction based on the video taken by the research colleague who does not know about the groups (outcome assessor).

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shahid Sadoughi University of Medical Sciences, Yazd

Street address
Vice-Chancellor of Research and Technology, Shahid Sadoughi University of Medical Sciences-Student Blvd-Imam Hossein Square -Yazd

City
Yazd

Province
Yazd

Postal code
۸۹۱۶۱۸۸۶۳۷

Approval date
2024-10-09, 1403/07/18

Ethics committee reference number
IR.SSU.REC.1403.082

Health conditions studied

1

Description of health condition studied
Pain during airway suctioning in infants

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Suction pain

Timepoint
3 minutes before suction and during and 2 minutes after suction

Method of measurement
Neonatal Infant Pain Scale

2

Description
The neonatal's heart rate

Timepoint
Three minutes before the start of suction and during and two minutes after suction

Method of measurement
Pulse oximetry

3

Description
Blood oxygen saturation percentage
Timepoint
Three minutes before the start of suction and during and two minutes after suction
Method of measurement
Pulse oximetry

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 31 infant in this group, from 3 minutes before the beginning of suction to 2 minutes after the end of suction, the airways were under aromatherapy with 2 drops of 10% rosehip essential oil made by Ide Daru Pars Company, which was poured on a cotton ball and a distance of 3 cm from the infant's nose. In both groups, the infant is placed in a lying position on the back and the head is placed in a non-rotating position. In both groups, due to the presence of secretions in the babies receiving CPAP with a nasopharyngeal tube, the oropharynx area will be suctioned once and then the nasopharynx area once, and during suctioning, the baby will be filmed using a Samsung mobile phone. Suction will be done using a 6 or 8 french catheter and the pressure of the device will be less than 80 mmHg. The suction time will be less than 6 seconds.
Category
N/A

2

Description
Control group: Infants were exposed 2 drops of sterile distilled water from a 5 ml vial (produced by Shahid Ghazi Pharmaceutical Company), poured onto a cotton pad and placed 3 cm away from the infant 's nose, from 3 minutes before until 2 minutes after the completion of suctioning.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Neonatal intensive Care Department of Shahid Sadoughi Hospital, Yazd
Full name of responsible person
Saeede Karamshahi
Street address
SHahid Sadouqi Hospital-Ibn Sina St- Ghandi Blvd- Yazd
City
Yazd
Province
Yazd
Postal code
8785789158
Phone
+98 35 3822 4000
Fax
+98 35 3822 4100
Email
sadoghi-hospital@ssu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Amir Hooshang Mehrparvar
Street address
Vice President of Research and Technology، Shahid Sadoughi University of Medical Sciences, Yazd-Imam Reza Educational Research Complex، Student Blvd، Imam Hossein Square
City
Yazd
Province
Yazd
Postal code
۸۹۱۶۱۸۸۶۳۷
Phone
+98 35 3628 8114
Email
dvc.research@ssu.ac.ir
Web page address
https://research.ssu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yazd 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
Yazd University of Medical Sciences
Full name of responsible person
Saeede Karamshahi
Position
Nurse
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
SHahid Dadalhi Alley-Aliabad Sazeman
City
Jiroft
Province
Kerman
Postal code
7861410043
Phone
9834436336
Email
saeedekaramshahi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Saeede Karamshahi
Position
Nurse
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
SHahid Dadalhi Alley-Ali Abad Sazeman
City
Jiroft
Province
Kerman
Postal code
7861410043
Phone
034436336
Email
saeedekaramshahi@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Saeede Karamshahi
Position
Nurse
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Shahid Dadalhi Alley-Ali Abad Sazeman
City
Jiroft
Province
Kerman
Postal code
7861410043
Phone
+98 34 4334 0115
Fax
Email
Saeedekararmshahi@gmail.com

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
There is no further information.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available