Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The Effect of Aromatherapy with Rosa Damascena Essential oil on Nutritional Tolerance and Weighing in Premature Infant in Neonatal Care Unit

Protocol summary

Study aim

Determining the effect of aromatherapy with rosa damascena essential oil on feeding tolerance and weighing of premature babies hospitalized in neonatal intensive care units

Design

A controlled, parallel-group, unblinded, quasi-randomized, phase 3 clinical trial on 60 preterm infants. Lottery was used for randomization.

Settings and conduct

The method of assigning two groups is a quasi-random clinical trial in the neonatal special care department of Imam Reza Hospital (in the form of a lottery for the first intervention or control group in two separate time periods). Olfactory stimulation in 4 times by the researcher and under the supervision of the corresponding nurse, starting with gavage in the form of a pad impregnated with the essence of the rose flower in the form of three drops on A cotton ball is applied and the gavage is completed.

Participants/Inclusion and exclusion criteria

Premature babies with a gestational age of 28 to 32 weeks Birth weight below 1500 grams and at least 1000 grams Breastfeeding Not having any life-threatening congenital abnormalities No necrotizing Enterocolitis No positive blood culture and meningitis No invasive mechanical ventilation

Intervention groups

Babies in the intervention group are weighed every morning with a specific scale and by the researcher. Gavage with breast milk will be done. The olfactory stimulation is performed at the beginning of gavage in the form of a pad impregnated with the essence of the rose flower in the form of three drops on a cotton ball and ends at the end of the gavage. This intervention continues for one week. Babies of the control group are weighed every morning with a specified scale by the researcher. Gavage with breast milk will be done every two hours according to the routine of the neonatal intensive care unit, and no intervention will be done for this group.

Main outcome variables

Nutritional Tolerance Weighing

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230408057853N1**
Registration date: **2023-04-29, 1402/02/09**
Registration timing: **prospective**

Last update: **2023-04-29, 1402/02/09**
Update count: **0**

Registration date

2023-04-29, 1402/02/09

Registrant information

Name

Asieh Bidel baze

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3259 6950

Email address

bidelas2@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-05, 1402/03/15

Expected recruitment end date

2024-03-05, 1402/12/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effect of Aromatherapy with Rosa Damascena Essential oil on Nutritional Tolerance and Weighing in Premature Infant in Neonatal Care Unit

Public title
The Effect of Aromatherapy with Rosa Damascena Essential oil on Nutritional Tolerance and Weighing in Premature Infant

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Premature babies with a gestational age of 28 to 32 weeks Birth weight below 1500 grams and at least 1000 grams Breastfeeding
Exclusion criteria:
Having any life-threatening congenital abnormalities Necrotizing Enterocolitis Positive blood culture and meningitis Invasive mechanical ventilation

Age
From **2 days** old to **10 days** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
School of Nursing and Midwifery - Mashhad University of Medical Sciences

Street address
Faculty of Nursing and Midwifery, Doctor's Crossroad, Ibn Sina Street, University of Mashhad, Khorasan Razavi

City
Mashhad

Province
Razavi Khorasan

Postal code
9137913199

Approval date
2023-03-14, 1401/12/23

Ethics committee reference number
IR.MUMS.NURSE.REC.1402.002

Health conditions studied

1

Description of health condition studied
Other feeding problems of newborn

ICD-10 code
p92.8

ICD-10 code description
Other feeding problems of newborn

Primary outcomes

1

Description
Nutritional Tolerance

Timepoint
Daily

Method of measurement
Nutritional Tolerance Check List

2

Description
Weighing

Timepoint
Daily

Method of measurement
Scales

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Infants in the intervention group every morning at 7:00-7:30 with a specific scales. They are weighed by the researcher. gavage with breast milk in 4 times (8 am, 12 noon, 4 pm and 8 pm) by the researcher. It will be done under the supervision of the relevant nurse. Olfactory stimulation will be done every time with the beginning of gavage as a pad soaked in the

essential oil of the rose.(prepared under the supervision of a pharmacist) is done as three drops on a cotton ball and at the end of gavage. It arrives This intervention continues for one week

Category

N/A

2

Description

Control group: Babies in the control group are weighed every morning at 7:30-7:30 a.m. with a specified scale by the researcher. Gavage with breast milk. Two hours will be done according to the routine of the neonatal intensive care unit, and no intervention will be done for this group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Emam Reza's Hospital

Full name of responsible person
Behnam Voshani Hamidreza

Street address
Ibn Sina Street, Imam Reza (AS) Hospital Square, Imam Reza (AS) Educational Research and Treatment Center, Khorasan Razavi

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bidelas2@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Ghayor Mobarhan Majid

Street address
Research and Technology Vice-Chancellor, building number one of Mashhad University of Medical Sciences (Qureshi), second floor, in front of University Avn 18, Mashhad, Khorasan Razavi

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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
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Behnam voshani Hamidreza

Position
Faculty member of the child and infant department

Latest degree
Master

Other areas of specialty/work
Nursery

Street address
No 5, Delavaran Avn 25, Mashhad

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
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Position
Faculty member of the child and infant department

Latest degree
Master

Other areas of specialty/work
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Person responsible for updating data

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Mashhad University of Medical Sciences
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Master's student in neonatal intensive care
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Bachelor
Other areas of specialty/work
Nursery
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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
There is no further information.
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available