

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 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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9137913316

**Phone**

+98 51 3854 3031

**Email**

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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9138813944

**Phone**

+98 51 3843 7840

**Email**

sram@mums.ac.ir

**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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Behnamhr@mums.ac.ir

**Person responsible for scientific 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

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

Mashhad University of Medical Sciences

**Full name of responsible person**

Asieh Bidel Baze

**Position**

Master's student in neonatal intensive care

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

No 79, Alimardani Avn 45, Mashhad, Khorasan Razavi

**City**

Mashhad

**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