

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Effectiveness and ineffectiveness of aromatherapy with damask rose extracts to reduce apnea in premature infants hospitalized in NICU ward of selected training hospitals of Esfahan in 2015

Protocol summary

Summary

This study will be done with aim to investigate the aromatherapy with damask rose extracts to reduce apnea in premature infants hospitalized in NICU ward of Investigate the aromatherapy with damask rose extracts to reduce apnea in premature infants hospitalized in NICU ward of Alzahra hospitals of Esfahan in 2015 hospitals of Esfahan in 2015. This study is a single blind clinical trial. 60 premature infants 29-33 weeks with 900 to 1500 gr weight that admission in NICU ward are selected by available methods and randomly will placed in two groups of experiment and control with 30 people. In the experimental group, in addition to conventional therapy, aromatherapy with damask rose extracts start on the second day of birth from 6Am and by pouring 2 drops of damask rose extracts 10% on linen that is located at a distance of 3 cm of infant head. In the control group in addition to conventional therapy, therapy on the second day of birth from 6Am and by pouring 2 drops of Distilled water on linen that is located at a distance of 3 cm of infant head and in the two groups at, 9.12, 15, 18, o'clock will repeat. In each time the heart rate and arterial oxygen recorded by the monitoring device and episodes of apnea with direct observation will be chart and record. Inclusion criteria: children between 3-29 weeks gestational age; birth weight between 900-1500 grams; The baby's blood hemoglobin level higher than 10g /dl; infants Parental consent; Lack of oxygen uptake through cpAP; no need for infant ventilator; lack of heart disease or any infection. Exclusion criteria were: discharge or death of an infant before the end of the intervention period; the incidence of respiratory symptoms and skin allergy during the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015121925601N4**

Registration date: **2016-01-04, 1394/10/14**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-01-04, 1394/10/14

Registrant information

Name

Saeideh Aghagoli

Name of organization / entity

Esfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 25366621496

Email address

aqagholi@nm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Esfahan university of medical science, research vice chancellor

Expected recruitment start date

2016-01-08, 1394/10/18

Expected recruitment end date

2016-05-09, 1395/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness and ineffectiveness of aromatherapy with damask rose extracts to reduce apnea in premature infants hospitalized in NICU ward of selected training hospitals of Esfahan in 2015

Public title

Investigate the aromatherapy with damask rose extracts to reduce apnea in premature infants hospitalized in NICU ward of selected training hospitals of Esfahan in 2015

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: infants between 29-33 weeks gestational age; birth weight between 900-1500 grams; The baby's blood hemoglobin level higher than 10g /dl;infants Parental consent; Lack of oxygen uptake through cpAP; no need for infant ventilator; lack of heart disease or any infection. Exclusion criteria were: discharge or death of an infant before the end of the intervention period; the incidence of respiratory symptoms and skin allergy during the study.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Randomly by tossing coin

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Committee Ethics, Esfahan University of Medical Sciences

Street address

Vice Chancellor for Research Affairs, Esfahan University of Medical Sciences, Hezarjarib Street

City

Esfahan

Postal code

Approval date

2015-08-31, 1394/06/09

Ethics committee reference number

IR.MUI.REC.1394.3.410

Health conditions studied

1

Description of health condition studied

Apnea

ICD-10 code

J98

ICD-10 code description

Other diseases of the respiratory system

Primary outcomes

1

Description

Heart rate

Timepoint

24 hours after birth, and 9, 12, 15, 18 hours after the first 24 hours

Method of measurement

By monitoring device

2

Description

Arterial blood oxygen saturation percent

Timepoint

24 hours after birth, and 9, 12, 15, 18 hours after the first 24 hours

Method of measurement

By monitoring device

3

Description

The number of episodes of apnea

Timepoint

24 hours after birth, and 9, 12, 15, 18 hours after the first 24 hours

Method of measurement

By direct observation

Secondary outcomes

empty

Intervention groups

1

Description

In the experimental group, in addition to conventional therapy, aromatherapy with damask rose extracts starton the second day of birth from 6Am and by pouring2 drops

of damask rose extracts 10% on linen that is located at a distance of 3 cm of infant head then at, 9,12, 15, 18, o'clock will repeat. In each time the heart rate and arterial oxygen recorded by the monitoring device and episodes of apnea with direct observation will be chart and record .

Category

Treatment - Drugs

2

Description

In the control group in addition to conventional therapy, therapy on the second day of birth from 6Am and by pouring 2 drops of Distilled water on linen that is located at a distance of 3 cm of infant head then at, 9,12, 15, 18, o'clock will repeat. In each time the heart rate and arterial oxygen recorded by the monitoring device and episodes of apnea with direct observation will be chart and record .

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Saeideh Aghagoli

Street address

City

Esfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Esfahan University of Medical Sciences

Full name of responsible person

Akram Mazaheri

Street address

Vice Chancellor for Research Affairs, Esfahan University of Medical Sciences, Street of Hezarjarib

City

Esfahan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Esfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Hazrate Masomeh Hospital

Full name of responsible person

Saeideh Agha Goli

Position

MSc student of Emergency care of infant

Other areas of specialty/work

Street address

Hazrate Masomeh Hospital, Before terminal, After Shahid Zeinodin Square

City

Ghom

Postal code

Phone

+98 21636665553

Fax

Email

Aghagoli1974@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Zohreh Ghazavi

Position

MSc of Nursing Training

Other areas of specialty/work

Street address

School of Nursing & Midwifery, Esfahan University of Medical Sciences, Hezarjarib Street

City

Esfahan

Postal code

Phone

+98 31 3792 3060

Fax

Email

ZOHRE_GHAZAVI@NM.MUI.AC.IR

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Saeideh Agha Goli

Position

MSc student of Emergency care of infant

Other areas of specialty/work

Street address

Hazrate Masomeh Hospital, Before terminal, After
Shahid Zeinodin Square

City

Ghom

Postal code

Phone

+98 21636665553

Fax

Email

Aghagoli1974@gmail.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty