

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

The effect of olfactory stimulation by vanillin on the range of apneal attacks in newborns affected by apnea of prematurity

Protocol summary

Summary

Apnea is one of the most common problems in premature newborns. The present study aimed to determine the effect of olfactory stimulation by vanilla on the rate of apnea incidence in premature newborns affected by apnea of prematurity. In this randomized controlled trial, 40 premature newborn are randomly divided into two test and control groups and are studied for 3 days. Inclusion criteria: aged less than 32 weeks; weight of less than 2000 grams; affected by apnea of prematurity without Response to Methyl Xanthine. Exclusion criteria: Distinguished apnea due to other reasons including acute infections; congenital heart illnesses; anemia ($Hb < 10$); consumers of sedative medicines; hypoglycemia. On first and third day, babies are monitored in terms of apnea quantity and arterial oxygen saturation changes and heartbeat. On second day, for babies in test group, 2 cc of vanilla solution is poured on a cotton piece each 12 hours and is put in incubator corner in 20-cm distance of baby head and for babies in control group, 2 cc of distilled water on a cotton and is put in 20-cm distance of baby head so that it has no contact with baby skin. The newborns of both groups will be continuously monitored for the number of apnea episodes and arterial blood oxygen saturation and heartbeat for 3 days.

General information

Acronym

AOP

IRCT registration information

IRCT registration number: **IRCT2015042821982N1**

Registration date: **2016-07-05, 1395/04/15**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-07-05, 1395/04/15

Registrant information

Name

Nayer Salmani

Name of organization / entity

Yazd University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research and technology, Yazd University of Medical Sciences

Expected recruitment start date

2016-07-05, 1395/04/15

Expected recruitment end date

2016-09-22, 1395/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of olfactory stimulation by vanillin on the range of apneal attacks in newborns affected by apnea of prematurity

Public title

Olfactory stimulation on apnea of prematurity

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Babies less than 32 weeks with weight less than 32 weeks who developed immature apnea and specialists distinguish immature apnea and started Methyl Xanthine for treatment and also 4-8 hours after receiving Methyl Xanthine are started into the study. Exclusion criteria: Distinguished apnea due to other reasons including acute infections; congenital heart illnesses; anemia (Hb<10); consumers of sedative medicines; hypoglycemia; hypocalcaemia are removed and babies with brain hemorrhage than grade 1; leukomalacia prefrontal; patent ductus arteriosus; chromosomal disorders; brain disorders and babies with allergy to vanilla smell are not introduced into the study. During the study, babies with Hemoglobin less than 10 and babies with apnea more than 3 are connected to cpap within one hour and are out of the study.

Age

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

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

randomization using a random number table.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Yazd University of Medical Sciences

Street address

Yazd University of Medical Science, Bahonar Square, Yazd

City

Yazd

Postal code

8916978477

Approval date

2016-05-09, 1395/02/20

Ethics committee reference number

IR.SSU.REC.1395.21

Health conditions studied

1

Description of health condition studied

apnea

ICD-10 code

p28.4

ICD-10 code description

Other apnoea of newborn

Primary outcomes

1

Description

Oxygen saturation

Timepoint

First, second and third day after birth in both control and experimental groups

Method of measurement

As percentage using a pulse oximeter

2

Description

heart rate

Timepoint

First, second and third day after birth in both control and experimental groups

Method of measurement

as beat using pulse oximetry

3

Description

episods of apnea

Timepoint

First, second and third day after birth in both control and experimental groups

Method of measurement

as beat using pulse oximetry

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: use 2 cc of liquid vanilla 64% within the incubator babies at a distance of 20 cm from the head and without skin contact.

Category

Prevention

2

Description

Control group: Use 2 ml of distilled water at a distance of

20 cm from the head and without skin contact

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

NICU, Shahid Sadoughi Hospital

Full name of responsible person

Sakine Yaghoobi

Street address

Ebnesina street, Riyazi square, Shahid Ghandi
Boulevard, Yazd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Yazd University of
Medical Sciences

Full name of responsible person

Nayer Salmani

Street address

Yazd University of Medical Sciences, Bahonar Square,
Yazd

City

yazd

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 of Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Nayer Salmani

Position

PHD of Nursing , Faculty Member

Other areas of specialty/work

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Web page address	<i>empty</i>
Sharing plan	Informed Consent Form
	<i>empty</i>
Deidentified Individual Participant Data Set (IPD)	Clinical Study Report
<i>empty</i>	<i>empty</i>
Study Protocol	Analytic Code
<i>empty</i>	<i>empty</i>
Statistical Analysis Plan	Data Dictionary
	<i>empty</i>