

# 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

Iran (Islamic Republic of)

###### Phone

+98 35 3824 6323

###### Email address

n.salmani@sbmu.ac.ir

##### 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

episodes 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**

Ebnasina street, Riyazi square, Shahid Ghandi  
Boulevard, Yazd

**City**

Yazd

## 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****Street address**

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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