

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

The effect of olfactory stimulation by vanillin on apnea prevention in premature infants admitted in the hospitals associated to shiraz university of medical sciences,2011

Protocol summary

Summary

This study focuses on the effects of olfactory stimulation by vanillin on apnea in premature newborn infants. In this study, 36 premature newborn infants with 2 postnatal age, randomly select in two groups of case and control. Saturated vanillin solution is used for case group and no interventions are performed on the control group. While babies in both groups are conveniently monitored within 5 days, the occurrence of apnea, the mean of heartbeat and the mean percentage of saturated arterial blood oxygen are measured by pulseoximetry.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201201078643N1**
Registration date: **2012-02-25, 1390/12/06**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-02-25, 1390/12/06

Registrant information

Name

Hajar Pourpulad

Name of organization / entity

Shiraz University of Medical Sciences, Fatemeh (P.B.U.H) School of Nursing & Midwifery

Country

Iran (Islamic Republic of)

Phone

+98 72 1223 7301

Email address

pourpuladh@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellery for Research affairs of the Shiraz University of Medical Sciences

Expected recruitment start date

2011-07-31, 1390/05/09

Expected recruitment end date

2012-01-30, 1390/11/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of olfactory stimulation by vanillin on apnea prevention in premature infants admitted in the hospitals associated to shiraz university of medical sciences,2011

Public title

The effect of olfactory stimulation on apnea in premature infants

Purpose

Prevention

Inclusion/Exclusion criteria

The inclusion criteria: Gestational age<36 weeks; Postnatal age: 2 day old; Birth weight<2500gr; No need for ventilator; Absence of congenital heart disease. The exclusion criteria: Hypocalcemia; Hypoglycemia;Hb<10; Need for ventilator; Intraventricular hemorrhage during intervention.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked
No information

Sample size
Target sample size: **36**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shiraz University of Medical Sciences

Street address
Shiraz

City
Shiraz

Postal code

Approval date
2011-11-03, 1390/08/12

Ethics committee reference number
CT-90-5789

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
Frequency of apnea

Timepoint
2-7 days of postnatal age

Method of measurement
Pulsoximetry

2

Description
Heart rate

Timepoint
2-7 days of postnatal age

Method of measurement
Pulsoximetry

3

Description
Oxygen saturation

Timepoint
2-7 days of postnatal age

Method of measurement
Pulsoximetry

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: On the first two days of the study a 0.04 grams of 2%-saturated vanillin solution is used every 12 hours and on the following three days, no vanillin solution is used with no intervention

Category
Prevention

2

Description
Control group: newborns are likewise under continuous monitoring but with no interventions.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Shiraz University of Medical Sciences

Full name of responsible person
Hajar Pourpulad

Street address
Fatemeh (P.B.U.H) School of Nursing & Midwifery, Namazi square, Shiraz

City
Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Gholamreza Hatam

Street address

Shiraz University of Medical Sciences, Setad, Shiraz

City

Shiraz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shiraz 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**

Shiraz University of Medical Sciences, Fatemeh
(P.B.U.H) School of Nursing & Midwifery

Full name of responsible person

Mrs Mitra Edraki

Position

Instructor, Department of Pediatric Nursing

Other areas of specialty/work**Street address**

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Full name of responsible person

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Position

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Shiraz University of Medical Sciences

Full name of responsible person

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Position

Master of Science

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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