Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 pulsoximetry.

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 weigth<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
Fatemeh (P.B.U.H) School of Nursing & Midwifery, Namazi square, Shiraz
City
Shiraz
Postal code
Phone
+98 71 1647 4257
Fax
Email
Mitraedraki@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences , Fatemeh (P.U.B.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
Fatemeh (P.B.U.H) School of Nursing & Midwifery, Namazi square, Shiraz
City
Shiraz
Postal code
Phone
+98 71 1647 4257
Fax
Email
Mitraedraki@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Hajar Pourpulad
Position
Master of Science
Other areas of specialty/work
Street address
Fatemeh (P.B.U.H) School of Nursing & Midwifery, Namazi square, Shiraz
City
Shiraz
Postal code
Phone
+98 71 1647 4257
Fax
Email
Pourpuladh@sums.ac.ir
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