Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of breast milk odor on transitonal time from gavage to oral feeding in premature infants hospitalized in Nicu of Valiasr and comprehensie women hospital in 1392 in Tehran

Protocol summary

Summary

Aim: The effect of odor stimulation with breast milk smell on feeding transitional time from gavage to oral feeding in premature infants hospitalized in intensive care unit in Valiasr and Comprehensive women hospital in Tehran in 2013 Inclusion and exclusion criteria: premature infants between 28-33 GA ; Minimmum weight of 1 kg ; Stable cardio-respiratory situation ; No ventriculare hemorahge ; No congenital anomallies Population and samples: 92 premature infants (46 infants in control group and 46 infants as intervene group) hospitalised in neonatal intensive care of Valiasr and Comprehensive women hospital from April to 29 Aguast 2013. Intervention:Odor stimulation with mother milk during gavage in study group. Primary result: Transitional feeding time , hospital stay and first breast feeding time is shorter in study group .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014031916538N1**
Registration date: **2014-03-19, 1392/12/28**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-03-19, 1392/12/28

Registrant information

Name

Atefeh Shamsi

Name of organization / entity

Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2253 3762

Email address

b.pouraboli@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Medical Science of Kerman University

Expected recruitment start date

2013-04-21, 1392/02/01

Expected recruitment end date

2013-09-06, 1392/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of breast milk odor on transitonal time from gavage to oral feeding in premature infants hospitalized in Nicu of Valiasr and comprehensie women hospital in 1392 in Tehran

Public title

The effect of mother' milk odor in gavage'weaning time in premature infants

Purpose

Supportive

Inclusion/Exclusion criteria

Incusion criteria:Infants with gestational age of 28-33 weeks ; Infants who had inability and weakness in sucking reflex according to Physician diagnosis ; Minimmum birth weight of 1 Kg ; Apgar score of more than 6 in minutes 1 and 5 ; Infants who were in an appropriate cardio-respiratory condition and had no O2

saturation drop Inclusion criteria: Dangeious anomallie for health ; Intra ventricular hemorrahages ; Resistance jundice in treatment

Age
From **28 years** old to **33 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **92**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Kerman University of Medical Sciences

Street address
Haft Bagh Steet, Afzalipoor Pardizeh,

City
Kerman

Postal code

Approval date
2013-04-21, 1392/02/01

Ethics committee reference number
92/02/کا

Health conditions studied

1

Description of health condition studied
Disorders related to short gestation and low birth weight, not elsewhere classified

ICD-10 code
P07

ICD-10 code description
Extremely low birth weight

Primary outcomes

1

Description
hospital stay

Timepoint
In discharge time

Method of measurement
Patient documentation

2

Description
first breast feeding time

Timepoint
Start of oral feeding

Method of measurement
cornometer

3

Description
weight

Timepoint
during study

Method of measurement
diital scale model tanita1583

4

Description
Transional time from gavage to oral feeding

Timepoint
In oral feeding start time

Method of measurement
Patient documentation

Secondary outcomes

empty

Intervention groups

1

Description
In study group we will stmulate infants with mothe'r milk odor pad during gavage in 9AM, 12MD, 3PM, 6PM during gavage feeding for minimmum 10 minute that will continiue to oral feeding time from breast.

Category
Other

2

Description
In control group we llnot do eny special intervention in spitr routin gavaging

Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Tehran Valiasr Hospital
Full name of responsible person
Street address
City
Tehran

2

Recruitment center
Name of recruitment center
Tehran Comprehensive Women Hospital
Full name of responsible person
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Kerman University of Medical Sciences
Street address
Haft Bagh Street, Afzalipoor Pardizeh, Kerman University of Medical Sciences
City
Kerman
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kerman 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
Kerman Nursing Facaulty
Full name of responsible person
Atefeh Shamsi
Position
MBA of Neonatal Intensive Care Nursing
Other areas of specialty/work
Street address
Haft Bagh Street, Afzalipoor Pardizeh, Kerman University of Medical Sciences
City
Kerman
Postal code
Phone
+98 21 2253 3762
Fax
Email
noor13500@yahoo.comb.pouraboli@kmu.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Nursing Facaulty of Kerman
Full name of responsible person
Atefeh Shamsi
Position
MBA of Neonatal Intensive Care Nursing
Other areas of specialty/work
Street address
Haft Bagh, Afzalipoor Pardizeh, Kerman University of Medical sciences
City
Kerman
Postal code
Phone
+98 21 2253 3762
Fax
Email
noor13500@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Kerman Nursing Facaulty
Full name of responsible person
Atefeh Shamsi
Position
MBA of Neonatal Intensive Care Nursing
Other areas of specialty/work
Street address
Shahid Shakeri Alley, Ostad Hassan Bana Street,Northen Magidieh.
City
Tehran
Postal code
Phone
00
Fax
Email
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