

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of breast milk odor on transitoral 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 1392 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 1392. 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

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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 transitoral 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

Inclusion 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: Dangerous anomalies for health ; Intra ventricular hemorrhages ; Resistance to 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 Street, Afzalipoor Pardizeh,

City

Kerman

Postal code

Approval date

2013-04-21, 1392/02/01

Ethics committee reference number

92/02/15

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

digital scale model tanita1583

4

Description

Transitional 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 stimulate infants with mother's milk odor pad during gavage in 9AM, 12MD, 3PM, 6PM during gavage feeding for minimum 10 minute that will continue to oral feeding time from breast.

Category

Other

2

Description

In control group we do not do any special intervention in spit routine gavage

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 Faculty

Full name of responsible person

Atefeh Shamsi

Position

MBA of Neonatal Intensive Care Nursing

Other areas of specialty/work

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Position

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Other areas of specialty/work

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00

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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