

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Effects of oral and physical stimulation on suck-swallow-respiration coordination and weight gain in preterm infants

Protocol summary

Summary

randomized , double blind ,Without placebo control , 3 Groups , The study population : born between 26-34 weeks gestational age . Inclusion criteria: born between 26-34 weeks gestational age : weight is less than 2500 gr : receiving only tube feeding : without congenital anomalies : without medical problem except prematurity: receiving only mother's milk exclusion criteria : Any problem with diagnosing doctor : If discharge is excluded : Unwillingness of parents to cooperate target sample size : 60 , data of intervention : mehr till dey 1393 , first group receive oral stimulation and take pacifier , second group receive oral - physical stimulation and take pacifier , third group they take pacifier for 10 days during a 14-day period.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014110219793N1**

Registration date: **2015-04-29, 1394/02/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-04-29, 1394/02/09

Registrant information

Name

Arezoo Chaeichi Tehrani

Name of organization / entity

Nursing University Of Fatima

Country

Iran (Islamic Republic of)

Phone

+98 71 3824 2589

Email address

chaeichia@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2014-09-23, 1393/07/01

Expected recruitment end date

2015-01-20, 1393/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of oral and physical stimulation on suck-swallow-respiration coordination and weight gain in preterm infants

Public title

oral and physical stimulation improve oral feeding

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: born between 26-34 weeks gestational age : weight is less than 2500 gr : receiving only tube feeding : without congenital anomalies : without medical problem except prematurity: receiving only mother's milk exclusion criteria : Any problem with diagnosing doctor : If discharge is excluded : Unwillingness of parents to cooperate

Age

From **28 days** old to **28 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double 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 University of Medical Sciences , Namazi Square
, Shiraz

City

Shiraz

Postal code

Approval date

2014-08-20, 1393/05/29

Ethics committee reference number

93-7094

Health conditions studied

1

Description of health condition studied

suck-swallow-respiration coordination

ICD-10 code

p07.3

ICD-10 code description

Other preterm infants

Primary outcomes

1

Description

suck-swallow-respiration coordination

Timepoint

Before , Middle and end of the intervention period

Method of measurement

Lists Of EARLY FEEDING SKILLS ASSESSMENT

2

Description

weight gain

Timepoint

daily

Method of measurement

Sinker

Secondary outcomes

1

Description

Length of hospitalization

Timepoint

in the intervening period

Method of measurement

day of hospitalization

Intervention groups

1

Description

the first groups receive only oral stimulation and take pacifier for 10 days during a 14-day period.

Category

Other

2

Description

the second groups receive oral - physical stimulation and take pacifier for 10 days during a 14-day period.

Category

Other

3

Description

control group take pacifier for 10 days during a 14-day period.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Zainab Hospital

Full name of responsible person

Ms Soltani

Street address

Holy 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

Headquarters Of Shiraz University Of Medical Sciences , Zand Ave , 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

Full name of responsible person

Mitra Edraki

Position

Master Of Nursing

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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