Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
Other areas of specialty/work
Street address
Nursing University Of Fatima , Main Square , Shiraz
City
Shiraz
Postal code
Phone
+98 71 3345 1978
Fax
Email
mitraedraki@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University Of Medical Sciences
Full name of responsible person
Mitra Edraki
Position
Master Of Nursing
Other areas of specialty/work
Street address
Nursing University Of Fatima , Main Square , Shiraz
City
Shiraz
Postal code
Phone
+98 71 3345 1978
Fax
Email
mitraedraki@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Shiraz University Of Medical
Full name of responsible person
Arezoo Chaeichi Tehrani
Position
Master Of Nursing
Other areas of specialty/work
Street address
Nursing University Of Fatima , Main Square Shiraz
City
Shiraz
Postal code
7178886167
Phone
+98 71 3824 2589
Fax
Email
a.chaeichi@yahoo.comchaeichia@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