

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

The comparison of two methods of finger feeding and cup feeding on the weight gain and achieve to independent oral nutrition premature infants

Protocol summary

Registration timing: **prospective**

Study aim

Determining the comparison of two methods of finger and cup feeding on weight gain and achieving independent oral feeding in premature infants admitted to the intensive care unit

Last update: **2022-05-09, 1401/02/19**

Update count: **0**

Registration date

2022-05-09, 1401/02/19

Design

A control trial with a control group with Parallel groups, one-way blind, randomized, on 90 patients, was used for limited type randomization under the title "Random Allocation Rule".

Registrant information

Name

Fatemeh Mirzaei badizi

Name of organization / entity

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Iran (Islamic Republic of)

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Settings and conduct

The study was performed on premature infants in the intensive care unit of Ali Ibn Abi Talib Hospital in Zahedan. By positioning the baby, we feed the baby and the baby doctor will not be aware of the assignment of the subjects.

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

Entry requirements: - Stable clinical condition (approved by the neonatologist) - Gestational age from 30 to 35 weeks - Have received full tube feeding
No entry requirements : - Infants with a history of underlying diseases - Infants taking sedatives - Infants with genetic syndromes and congenital anomalies of the head and neck

Expected recruitment start date

2022-06-04, 1401/03/14

Expected recruitment end date

2023-03-05, 1401/12/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Intervention groups

In the intervention groups, by positioning the infant, the infant begins to be fed by finger or cup method, and the control group receives its routine feeding through gavage.

Main outcome variables

weight gain: Achieve independent oral nutrition

Scientific title

The comparison of two methods of finger feeding and cup feeding on the weight gain and achieve to independent oral nutrition premature infants

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220302054171N1**

Registration date: **2022-05-09, 1401/02/19**

Public title

Comparison of the effectiveness feeding methods in premature infants

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Stable clinical condition Gestational age from 30 to 35 weeks Receive OGT feeding completely

Exclusion criteria:

Infants with a history of underlying diseases Infants with sedative Receive Infants with neurological diseases and congenital head and neck abnormalities Infants with genetic syndromes Infants with underlying diseases

Age

From **1 day** old to **28 days** old

Gender

Both

Phase

N/A

Groups that have been masked

- Care provider

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be placed in intervention and control groups by the limited randomization method called "Random allocation rule"; In this way, 90 color cards identifying the study groups (red card of intervention 1, blue card of intervention 2 and white card of control group) will be prepared for the total number of patients studied and the patient will be selected based on the color cards. Eligible will be placed in groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the fact that only the diagnosis and decision about starting oral feeding and the number of times of oral feeding per day is made by the neonatologist present in the ward, so they will not be aware of the allocation of subjects in the two intervention groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Zahedan University of Medical Sciences

Street address

Main campus of medical sciences, Dr. Hesabi Square

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Approval date

2022-04-17, 1401/01/28

Ethics committee reference number

IR.ZAUMS.REC.1401.029

Health conditions studied

1

Description of health condition studied

Weight gain and achievement of independent oral nutrition in premature infants

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Weigh gain of premature infants through the Beurer calibrated scale in the neonatal intensive care unit

Timepoint

Weight measurement at the beginning of the intervention and 72 hours after feeding

Method of measurement

Beurer calibrated scales

2

Description

Achieve to independent oral nutrition

Timepoint

Assessing the frequency of achieving oral independence 72 hours after the start of the nutritional intervention

Method of measurement

Breastfeeding

Secondary outcomes

1

Description

Adequacy of nutrition

Timepoint

Before the intervention and 72 hours after the intervention

Method of measurement

Calibrated cup of Espadana company

Intervention groups

1

Description

First Intervention group: The meaning of cup feeding is that breast milk is prepared in a graduated plastic cup from Espadana company. While sitting, hold the baby slightly backwards, hold the cup of milk in front of the baby's lips, and gently place it on the baby's lower lip in the gap between the lower lip and gums. Then tilt the cup so that the milk reaches the baby's lips. The premature baby eats the milk from the cup with forward movements of the tongue.

Category

N/A

2

Description

Second Intervention group: For finger feeding, this is how it is done: Tube number five is used, which is fixed with a thin adhesive tape on the little finger of the researcher, one end of which is attached to the finger and the other end to the 5 cc of Laurel Ava syringe. Hold the baby upright and gently pour the milk into the baby's mouth each time, with the milk between the gums and cheeks or on the baby's tongue. The baby is then allowed to swallow the milk.

Category

N/A

3

Description

Control group: Receive routine ward care

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Ibn Abi Talib hospital

Full name of responsible person

Fatemeh Mirzaei Badizi

Street address

In front of Imam Khomeini Mosque, Persian Gulf Highway

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Dr. Noor Mohammad Bakhshani

Street address

Campus of Medical Sciences, Dr. Hesabi Square

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Zahedan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Mahin Naderifar

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available