

# 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 3244 4820

##### Email address

fa.mirzaei.997@gmail.com

#### 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

#### 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.

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Main outcome variables

weight gain: Achieve independent oral nutrition

#### Trial completion date

empty

#### General information

#### 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

#### 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

**City**

Zahedan

**Province**

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**Postal code**

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+98 54 3329 5765

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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

### Contact

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Zahedan University of Medical Sciences

**Full name of responsible person**

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**Position**

Assistant Professor

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## Person responsible for updating data

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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