

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

The Effect of Oral massage and Non Nutritive Sucking on Independent Oral Feeding Performance in Preterm Infants Hospitalized in NICU of Tabriz Al-Zahra hospital

Protocol summary

Summary

The Objective of this one blinded randomized clinical trial is to compare two methods of oral massage and non nutritive sucking on independent oral feeding performance of preterm infants hospitalized in NICU. After having parental informed consent, 81 infants who are eligible will be randomly allocated into the following two intervention groups (oral massage, non nutritive sucking) and control group. Newborns in oral massage group were received pri and intraoral massage at least for 10 days, each time for 10 minutes twice daily by a one of nurse researcher. Newborns in non nutritive sucking group were received sucking of researcher or mother thumb at least for 10 days, each time for 5 minutes four times daily before gavages. Newborns in control group receive routine care. After 10 days, by visit of neonatologist were started oral feeding. Infant's behavioral state, the ability to maintain physiologic stability, time of attaining to independent oral feeding, oral feeding frequency, oral feeding duration and duration of hospitalization is assessed. A criterion for independent oral feeding is 8 times a day oral feeding.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201105304613N7**
Registration date: **2012-06-10, 1391/03/21**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-06-10, 1391/03/21

Registrant information

Name

Sousan Valizadeh Dehkharghani

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

009804134751706- 34796770

Email address

valizades@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2012-02-20, 1390/12/01

Expected recruitment end date

2012-09-18, 1391/06/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Oral massage and Non Nutritive Sucking on Independent Oral Feeding Performance in Preterm Infants Hospitalized in NICU of Tabriz Al-Zahra hospital

Public title

The Effect of Oral massage and Non Nutritive Sucking on Independent Oral Feeding Performance in Preterm Infants Hospitalized in NICU of Tabriz Al-Zahra Hospital

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria: 28-32 weeks gestation age, have

Stability of physiological , doesn't present illness and congenital abnormalities, especially in the jaw, mouth and palate as well as heart and lung disease are not serious, not be NPO and receiving full tube feeding. Exclusion Criteria: If the diagnosis of neuromuscular problems, cardiovascular disease and congenital anomalies in infants or being NPO during of study or having effective nutritive sucking in first 5 days of intervention, infants will be excluded.

Age

From **28 years** old to **32 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **81**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

Ethics committee, Third Floor, Building 2, Tabriz University of Medical Sciences, ,Department of Research Deputy, Golgasht St,Tabriz .

City

Tabriz

Postal code

Approval date

2011-07-25, 1390/05/03

Ethics committee reference number

5/4/3641

Health conditions studied

1

Description of health condition studied

Other preterm infants

ICD-10 code

P07.3

ICD-10 code description

28 completed weeks or more but less than 37 completed weeks (196 completed days but less than 259 completed days) of gestation.

Primary outcomes

1

Description

time of attaining to independent oral feeding

Timepoint

each day to achieving independent oral feeding

Method of measurement

observation and recording

2

Description

oral feeding frequency

Timepoint

daily

Method of measurement

Observation and recording

3

Description

oral feeding duration

Timepoint

Daily

Method of measurement

Observation and recording

Secondary outcomes

1

Description

duration of hospitalization

Timepoint

after the intervention

Method of measurement

observation and recording

Intervention groups

1

Description

Newborns in oral massage group were received pri and intraoral massage at least for 10 days, each time for 10 minutes twice daily.

Category

Treatment - Other

2

Description

Newborns in non nutritive sucking group were received

sucking of researcher or mother thumb at least for 10 days, each time for 5 minutes four times daily before gavage.

Category

Other

3

Description

Newborns in control group receive routine care.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital

Full name of responsible person

Iran Amirteimory

Street address

Educational and Therapeutic Center Al-Zahra,
Baghshomal Crossroads, Artesh Street

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Deputy of Medical Sciences of Tabriz
University

Full name of responsible person

Dr Hosien Ebrahimi

Street address

Nursing & Midwifery Faculty

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research Deputy of Medical Sciences of Tabriz University

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Iran Amirteimory

Position

Student of Master degree in Neonatal Intensive Care
Nursing

Other areas of specialty/work

Street address

Nursing And Midwifery Faculty

City

Tabriz

Postal code

4419951668

Phone

+98 41 1479 0365

Fax

Email

iamirteimory@yahoo.com

Web page address

Person responsible for updating data

Contact

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