

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

The Effect of Developmental Care on Short and Long- Term Outcomes and Mother-Infant Attachment in Preterm Infants.

Protocol summary

2014-08-04, 1393/05/13

Summary

The aim of this study is to determine the impact of developmental care on neonatal outcomes and maternal-child attachment in preterm infants. This study involved three groups with 35 cases in each group that will take place on babies with gestational age of 26 to 32 weeks with a birth weight less than 1500 g, born in Tabriz Alzahra Hospital, mechanical ventilation or CPAP initiated within 3 hours of birth and continued for at least 24 hours. The selections of control samples will be based on medical records of infants are admitted to the Alzahra NICU from September 2013 until the end of January 2014 (at this time not doing any developmental care). The selection of Intervention group 1 (Infants who received developmental care in NICU) and Intervention group 2 (Infants who received developmental care from delivery or operating room) will be based on inclusion and exclusion criteria and will be done from 2014 July. The sampling method in three groups will be based on convenience sampling. Outcomes will be include: clinical outcomes, infant development status based on ASQ at the corrected age of months 4, 8 and 12, development status based on the Bayley scale at corrected age of months 12 , maternal- child attachment status at corrected age of month 12 and finally cerebral structure status by MRI at the corrected age of month 12.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201405175563N5**

Registration date: **2014-08-04, 1393/05/13**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

Registrant information

Name

Elaheh Ouladsahebmadarek

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1554 1221

Email address

madarek@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2013-08-23, 1392/06/01

Expected recruitment end date

2016-03-20, 1395/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Developmental Care on Short and Long-Term Outcomes and Mother-Infant Attachment in Preterm Infants.

Public title

The Effect of Developmental Care on Infant Outcomes and Mother-Infant Attachment in Preterm Infants.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: The tendency of parents to participate

in the study; Gestational age equal or less than 32 weeks with birth weight less than 1500 g; Infant is born in Tabriz Alzahra Hospital; Lack of maternal use of alcohol or drugs during pregnancy; Initiation of mechanical ventilation or CPAP within 3 hours of birth and continued for at least 24 hours. Exclusion criteria: Chromosomal abnormalities and congenital anomalies; Severe congenital infections; Infants need surgery; Dissuasion of parents from continuing to participate in the study.

Age

From **6 months** old to **7 months** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **105**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tabriz University of Medical Sciences

Street address

Golgasht Street

City

Tabriz

Postal code

Approval date

2014-06-26, 1393/04/05

Ethics committee reference number

9345

Health conditions studied

1

Description of health condition studied

Neonatal outcome

ICD-10 code

P 28.5

ICD-10 code description

Respiratory failure of newborn

Primary outcomes

1

Description

Length of stay in NICU

Timepoint

During discharging from the NICU

Method of measurement

Using researcher made questionnaire

2

Description

The need for respiratory support

Timepoint

During the stay in the NICU

Method of measurement

Using researcher made questionnaire

Secondary outcomes

1

Description

Development of Infant

Timepoint

At corrected ages of 4,8,12 and 24 months

Method of measurement

by Ages and Stages Questionnaire and Bailey Scale

Intervention groups

1

Description

Intervention group 1: Infants in this group will be received developmental care that includes the reducing light, reducing environment noise, nesting, manipulating of infants with slow movements, etc in NICU.

Category

Prevention

2

Description

Intervention group 2: Infants in this group will be received developmental care from operating or delivery room. Developmental care in the delivery or operating room include: increasing operating and delivery room temperature (25 ° C), reduction of light, getting and delivering the baby horizontally, delayed cord clamping 45-60 seconds, gentle manipulation the baby in the delivery or operating room

Category

Prevention

3

Description

Control group: Infants in this group will be received routine care in operating and delivery room and NICU.

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Alzahra Hospital

Full name of responsible person

Shirin Hasanpour Shater

Street address**City**

Tabriz

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice Chancellor for Research of Tabriz University of Medical Sciences

Full name of responsible person

Dr Mohammadreza Rashidi

Street address

Golgasht Ave.

City

Tabriz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice Chancellor for Research of Tabriz 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**

Tabriz University of Medical Sciences

Full name of responsible person

Shirin Hasanpour Shater

Position

Midwifery Instructor

Other areas of specialty/work**Street address**

South Shariati Ave., Nursing and midwifery Faculty

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tabriz University of Medical sciences

Full name of responsible person

Dr Elaheh Ouladsahebmadarek

Position

Associate Prof. of Ob & Gyn

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

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Position

Midwifery Instructor

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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