

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of clustered care on physiological and behavioral responses in preterm infants: Randomised cross-over clinical trial

Protocol summary

Summary

Objective: Evaluate the effect of clustered care with different number of procedures (stressor scores) on physiological and behavioral responses of preterm infants. Design: Randomized; three periodic three groups crossover design. Setting and conduct: At any time, after devoting 30 minutes to relax, breathing score will be calculated for infants, one of clustered cares will be done, two cameras, one focused on the infant's face and body and other focuses on monitor screen, will take filming two minutes before the clustered care, during clustered care and by two minutes after it. Then will be evaluated behavioral responses and physiological measures (heart rate, respiratory rate, blood oxygen saturation) from recorded films. Intervention: clustered cares with three, four and five procedures. Inclusion criteria: Infants' age between 30-32 weeks at birth and 32 weeks during the study; having a minimum weight of 1000 g at the time of study; consent form is signed by parents; absence of congenital anomalies; written order of a physician for gavage; without prohibited changing position; respiratory score lower than or equal to five; no status of asphyxia. Exclusion criteria: Infants with IVH grade 3 and 4; periventricular leukomalacia; need for mechanical ventilation; steady decline in HR and O2 sat and respiratory rate of normal range; septicemia or be transferred to the neonatal unit refrain from further testing. Main outcome measures (variables): Behavioral and physiological responses of infant during clustered care and by two minutes after it.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201302058315N5**

Registration date: **2013-05-13, 1392/02/23**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-05-13, 1392/02/23

Registrant information

Name

Leila Valizadeh

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1479 6770

Email address

valizadehl@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2013-05-15, 1392/02/25

Expected recruitment end date

2013-06-21, 1392/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of clustered care on physiological and behavioral responses in preterm infants: Randomised cross-over clinical trial

Public title

The effect of clustered care on physiological and behavioral responses in preterm infants

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Being admitted to the NICU; infants' age between 30-32 weeks at birth and 32 weeks during the study; having a minimum weight of 1000 g at the time of study; consent form is signed by parents; absence of congenital anomalies; written order of a physician for gavage; without prohibited changing position; respiratory score lower than or equal to five; no status of asphyxia Exclusion criteria: Infants with IVH grade 3 and 4; periventricular leukomalacia; need for mechanical ventilation; steady decline in HR and O2 sat and respiratory rate of normal range; septicemia or be transferred to the neonatal unit refrain from further testing.

Age

From **30 years** old to **32 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size:

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tabriz University of Medical Sciences Ethics Committee

Street address

Golgasht Street, Tabriz

City

Tabriz

Postal code

Approval date

2013-05-06, 1392/02/16

Ethics committee reference number

9220

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

Behavioral responses

Timepoint

Two minutes before the start of clustered care, during the clustered care and by two minutes after it

Method of measurement

The camera is already installed

2

Description

Physiological responses

Timepoint

Two minutes before the start of clustered care, during clustered care and by two minutes after it

Method of measurement

The camera is already installed

Secondary outcomes

empty

Intervention groups

1

Description

Clustered care including four invasive procedures (stressor score ten) consists of measuring axillary temperature (2 points), change location of pulse oximeter probe (2 points), gavage (3 points) and changing position (3 points)

Category

Other

2

Description

Clustered care including three invasive procedures (stressor score seven) consists of measuring axillary temperature (2 points), change location of pulse oximeter probe (2 points) and changing position (3 points)

Category

Other

3

Description

Clustered care including five invasive procedures (stressor score thirteen) consists of measuring axillary temperature (2 points), change location of pulse oximeter probe (2 points), weighing (3 points), gavage (3 points) and changing position (3 points)

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Educational and Therapeutic Center Al-Zahra

Full name of responsible person

Poor Ashoori- Sheryzad

Street address

Artesh Street, Baghshmal Crossroads, Tabriz

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tabriz University of Medical Sciences

Full name of responsible person

Dr Mohammad Reza Rashidi

Street address

Golgasht Street, Tabriz

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, 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 School of Nursing and Midwifery

Full name of responsible person

Marziyeh Avazeh

Position

Student of Master degree in Neonatal Intensive Care Nursing

Other areas of specialty/work

Street address

Shariati South Street, Tabriz

City

Tabriz

Postal code

Phone

00984262232793, 00989141284596

Fax

Email

m.avazeh@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz School of Nursing and Midwifery

Full name of responsible person

Dr Leila Valizadeh

Position

Associate Professor

Other areas of specialty/work

Street address

Shariati South Street, Tabriz

City

Tabriz

Postal code

Phone

+98 41 1479 6770

Fax

Email

Valizadehl@tbzmed.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tabriz School of Nursing and Midwifery

Full name of responsible person

Marziyeh Avazeh

Position

Student of Master degree in Neonatal Intensive Care Nursing

Other areas of specialty/work

Street address

Shariati South Street, Tabriz

City

Tabriz

Postal code

Phone

Fax

Email

m.avazeh@yahoo.com

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