

# 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

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00984262232793, 00989141284596

#### Fax

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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

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Valizadehl@tbzmed.ac.ir

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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*