

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### Comparison of the effect of massage and prone positioning on changes of HR & SaO2 among hospitalized preterm neonates in NICUs .

#### Protocol summary

##### Study aim

1- To compare the effect of massage and prone position on HR & SaO2 changes in preterm infants.

##### Design

The subjects were selected through convenient sampling and the sample size was calculated by sample size formula as 21 subjects in 3 group. With regard to possible subjects' drop , 25 subjects were assigned to each group. Group 1 is position, 2 is massage and 3 is control. Then, the neonates meeting the inclusion criteria were assigned to each group (total of three groups) through random computation. In position group, infants will lay in pron position for 1 hour and then will monitor. In massage group, they will massaged based on Field massage protocol and then will monitor for 1 hour. In control group, infants will monitor without any intervention for 1 hour. The HR and SpO2 will record every 15 min.

##### Settings and conduct

This is an interventional cross- sectional double blind study conducted on all neonates who are hospitalized in NICUs of selected hospitals affiliated to Alborz University of Medical Sciences.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Complete infant's vigilance; upper 34 wk; >1500- gr; ability of breastfeeding; RDS diagnosis; O2 dependency; need for hospitalization more than 1 week; SaO2 > 89%. Exclusion criteria: touch contraindication; derm complications; Paralysis of the limb; major congenital anomalies; asphyxia and addiction of mother; CHD; active bleeding & depended respiratory distress.

##### Intervention groups

Position group: Subject will be lay on prone position for 1 hour and during this time, the HR and SaO2 variation, will record every 15 min. Massage group: After receiving massage according Tiffany Field technique, the HR and SaO2 variation, will record every 15 min, during 1 hour monitoring. Control group: Subject will monitoring for 1

hour without any intervention and during this time, the HR and SaO2 variation, will record every 15 min.

##### Main outcome variables

Changes of HR and SaO2 in hospitalized neonates in NICU

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20130202012346N2**

Registration date: **2018-01-05, 1396/10/15**

Registration timing: **retrospective**

Last update: **2018-01-05, 1396/10/15**

Update count: **0**

##### Registration date

2018-01-05, 1396/10/15

##### Registrant information

##### Name

Azamolmolouk Elsagh

##### Name of organization / entity

Isfahan University of Medical Science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 1792 2964

##### Email address

a\_elsagh@nm.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Alborz University of Medical Science

##### Expected recruitment start date

2017-07-23, 1396/05/01

##### Expected recruitment end date

2017-09-23, 1396/07/01  
**Actual recruitment start date**  
2017-07-23, 1396/05/01  
**Actual recruitment end date**  
2017-10-12, 1396/07/20  
**Trial completion date**  
empty

**Scientific title**  
Comparison of the effect of massage and prone positioning on changes of HR & SaO2 among hospitalized preterm neonates in NICUs .

**Public title**  
comparison of the effect of massage and prone positioning on VS variation

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Complete infant's vigilance > 2500gr 34 - 37 wk ability of breastfeeding Hospitalization more than 1 week RDS diagnosis O2 dependency The lower limit of SaO2 = 89% Haven't any touch contraindication  
**Exclusion criteria:**  
<1500 gr major congenital anomalies asphyxia limb Paralysis >37 wk addiction of mother CHD and dependent disease active bleeding derm complications limb Paralysis

**Age**  
From **1 day** old to **1 month** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**  
Target sample size: **75**  
Actual sample size reached: **75**  
More than 1 sample in each individual  
Actual sample size in each individual: **1**  
every intervention is individualized for a neonate

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
The subjects were selected through convenient sampling by drawing without replacement. With regard to 75 possible subjects' drop , 25 subjects were assigned to each group. It was listed the number and name of the group, on each drop( Position group:1, Massage group:2, control group:3). For each infant, a sheet is drawn randomly.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
All stages of intervention will record by a Panasonic handy cam. Then, recorded films would observed and

scored by a person who will blind to assignment of neonates to three different groups. To prevent bias and prejudice, this person will unaware of the group, which the neonate she will watching belonged to, so that scoring was made based on codes

**Placebo**  
Not used  
**Assignment**  
Parallel  
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Alborz University of medical Science

##### Street address

Faculty of nursing & midwifery. First Golestan- North Esteraki- Baghestan Blvd

##### City

Karaj

##### Province

Alborz

##### Postal code

3146883811

#### Approval date

2017-06-22, 1396/04/01

#### Ethics committee reference number

Abzums.Rec.1396.47

## Health conditions studied

### 1

#### Description of health condition studied

prone position

#### ICD-10 code

#### ICD-10 code description

### 2

#### Description of health condition studied

massage

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

HR

#### Timepoint

1min- 15th min- 30th min- 45th min- 60th min

#### Method of measurement

Pulse Oximetry

## 2

### **Description**

SaO2

### **Timepoint**

1min-15th min- 30th min- 45th min- 60th min

### **Method of measurement**

pulse Oximetry

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

First Intervention group : Position group: Subjects will be laid on prone position for 1 hour, then during this time, the HR and SaO2 variation, will be recorded every 15 min. This intervention will be done for 5 consecutive days in a specific hour for every infant.

#### **Category**

Other

### 2

#### **Description**

Intervention group 2nd: Massage group: After receiving massage according to Tiffany Field technique, the HR and SaO2 variation, will be recorded every 15 min, during 1 hour monitoring. This intervention will be done for 5 consecutive days in a specific hour for every infant.

#### **Category**

Other

### 3

#### **Description**

Control group: Subject will be monitored for 5 consecutive days in a specific hour, during 1 hour without any intervention and the HR and SaO2 variation, will be recorded every 15 min.

#### **Category**

Other

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Hazrat Ali Hospital

##### **Full name of responsible person**

Haleh Hatam Gooya

##### **Street address**

Se Rah Azimiye- Hazrat Ali Hospital

##### **City**

Karaj

##### **Province**

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### 2

#### **Recruitment center**

##### **Name of recruitment center**

Kamali hospital

##### **Full name of responsible person**

Azamolmolouk Elsagh

##### **Street address**

Faculty of nursing and midwifert

##### **City**

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## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Alborz university of Medical science

##### **Full name of responsible person**

Dr Mohammad Nuri Sepehr

##### **Street address**

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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**

Alborz university of Medical science

#### **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**  
Alborz University of Medical Science  
**Full name of responsible person**  
Azamolmolouk Elsagh  
**Position**  
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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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**Web page address**

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is 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

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is 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

No - There is not a plan to make this available

### Title and more details about the data/document

Demographic information of cases include of: age, sex & weight of neonates will report in tables.

### When the data will become available and for how long

6 month after publish of results.

**To whom data/document is available**

Staff nurses and Master of sciences that are involve with neonates.

**Under which criteria data/document could be used**

E-Mail request. Following the approval of the university law will apply.

**From where data/document is obtainable**

Deputy of Research of University

**What processes are involved for a request to access data/document**

Requesting to Deputy of Research of University and doing administrative process

**Comments**