

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The comparison of swaddling and nesting position in neonate abstinence syndrom in weight gain , stress and finnegan score

#### Protocol summary

##### Summary

The aim of this study was to compare the joints and nest on stress and weight gain and Finnegan score addicted baby with mother. A total of 30 eligible infants: infants 32 weeks and more addicted mothers who are not intubated and major malformations Ndashtndv in hospital neonatal intensive care unit of Ghaem and Imam Reza & Hashemi Nejad had Mshhdbstry will be selected. Before the start of the study will Shd.nvzadan written consent of mothers randomly in groups or nests will Grft.mtalh swaddling baby clothing will be replaced at intervals. Children from 8 am to 8 pm 8 pm to 8 am Shvdvaz put the butt u-shaped nest is placed. Every morning before feeding baby weight, measured with scales Seca. Weight per day up to seven days and recorded. Finnegan evaluation 24 hours after admission for two to four hours and then carried out. If up to 48 hours, the score remained less than eight, every eight hours for five to seven days of evaluation continues. Agrnmrh more than 8, the number of scoring every two hours (up to 24 hours after the last score 8) increases. Stress from observation sheet used to evaluate the collected data analysis is performed using spss software version 16.

#### General information

##### Acronym

The comparison of swaddling and nesting position in neonate abstinence syndrom in weight gain

##### IRCT registration information

IRCT registration number: **IRCT2016062028553N1**

Registration date: **2017-11-12, 1396/08/21**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-11-12, 1396/08/21

#### Registrant information

##### Name

zohre araghi

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3841 2081

##### Email address

araghiz931@mums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Mashhad university of medical science

#### Expected recruitment start date

2016-05-07, 1395/02/18

#### Expected recruitment end date

2017-05-08, 1396/02/18

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The comparison of swaddling and nesting position in neonate abstinence syndrom in weight gain , stress and finnegan score

#### Public title

The comparison of swaddling and nesting position in neonate abstinence syndrom in weight gain , stress and finnegan score

#### Purpose

Supportive

#### Inclusion/Exclusion criteria

Inclusion criteria: gestational age of 32 weeks and more, the need for mechanical ventilation, such as the lack of

major malformations (MMC and meningomyelocele), absence of severe cardiovascular disorders. myarhay outputs are: personal fulfillment parents to discharge the baby, the baby died, infants who have severe cardiovascular disorders. Babies with sepsis and metabolic disorders, sedative and hypnotic drugs to infants requiring phototherapy are Gyrnd.nvzadany

#### Age

From **8 months** old to **10 months** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

No information

#### Sample size

Target sample size: **30**

#### Randomization (investigator's opinion)

N/A

#### Randomization description

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Crossover

#### Other design features

Babies with addicted mothers are selected by simple random assignment. One in one They fall into one of the two groups of sandals and nests.

## Secondary Ids

### 1

#### Registry name

مرکز ثبت کارآزمایی بالینی ایران

#### Secondary trial Id

28553

#### Registration date

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

The Ethics Committee of Mashhad University of Medical Sciences

##### Street address

University Street

##### City

mashhad

##### Postal code

13944-91388

#### Approval date

2016-05-07, 1395/02/18

#### Ethics committee reference number

941357

## Health conditions studied

### 1

#### Description of health condition studied

Weight gain and stress and Fingen baby with addicted mother

#### ICD-10 code

p96.1

#### ICD-10 code description

Drug withdrawal syndrome in infant of dependent mother Neonatal abstinence syndrome

## Primary outcomes

### 1

#### Description

Weighing

#### Timepoint

Seven days

#### Method of measurement

Weight with weight

## Secondary outcomes

### 1

#### Description

Stress

#### Timepoint

Seven days

#### Method of measurement

Observation sheet tool

### 2

#### Description

finnegan

#### Timepoint

5 to 7 days

#### Method of measurement

finnegan form

## Intervention groups

### 1

#### Description

#### Category

Other

### 2

#### Description

Addicted maternal newborns are selected by simple random assignment. As one in between They fall into one of the two groups of buttocks or nests. In the nest group, the neonate is placed in the yoke in the first day. The second three days are placed inside the gondolas. The baby is weighed up to 7 days a day. The stress of a baby is measured up to 7 days. The baby's deprivation

according to the Finagan form and according to the score obtained from 5 days to 7 days for the infant is completed.

**Category**

N/A

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Ghaem Hospital in Mashhad

**Full name of responsible person**

zohre araghi

**Street address**

Faculty of Nursing and Midwifery of Mashhad

**City**

mashhad

**2**

**Recruitment center**

**Name of recruitment center**

Imam Reza Hospital (AS)

**Full name of responsible person**

zohre araghi

**Street address**

Ibn Sina Street / Imam Reza Square

**City**

mashhad

**3**

**Recruitment center**

**Name of recruitment center**

Hashemi Nejad Hospital

**Full name of responsible person**

zohre araghi

**Street address**

Shahid Hasheminejad Street

**City**

mashhad

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Deputy of Research of Mashhad University of Medical Sciences

**Full name of responsible person**

Tayyib Reyhani

**Street address**

School of Nursing and Midwifery

**City**

Mashhad

**Grant name**

**Grant code / Reference number**

941357

**Is the source of funding the same sponsor**

**organization/entity?**

Yes

**Title of funding source**

Deputy of Research of Mashhad 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**

Faculty of Nursing and Midwifery, Mashhad University of Medical Sciences

**Full name of responsible person**

zohre araghi

**Position**

Masters of Neonatal Care

**Other areas of specialty/work**

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Associate Professor

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School of Nursing and Midwifery

**Full name of responsible person**

araghi zohre

**Position**

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**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*