

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jul 2026

### Effects of massage on weight gain in premature infants at Imam Khomeini Hospital in 1389

#### Protocol summary

##### Summary

The aim of this study was to investigate the effects of massage on weight gain of premature infants in Imam Khomeini Hospital in 2012 -2013. Inclusion criteria: All of prematurity and parental consent and exclusion: infants need to have surgery or respiratory support-infant have anomaly- congenital heart malformation-central nervous system dysfunction- infants are not able to feed orally. This study includes 34 cases that divided on 2 groups of 17 infants under 36 weeks and was weighing less than 1500 gram thus during the study period was 15 days, 3 times daily, 15 minutes massage one hour after each feeding by massage therapists were trained on the intervention group. To ensure validity and avoid mistakes, each infant had different massage therapists not a fixed massage therapists. At the end of the study the rate of weight gain, the amount of calories and number of infants had ability to breast feeding have been studied and two groups are compared

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201208059568N2**  
Registration date: **2012-11-21, 1391/09/01**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2012-11-21, 1391/09/01

##### Registrant information

##### Name

Golnaz Rezaeizadeh

##### Name of organization / entity

Maternal Fetal Neonatal Research Center,Tehran

University of Medical Sciences, Tehran, Iran

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6119 2357

##### Email address

mfnhrc@tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Tehran University of Medical Sciences

##### Expected recruitment start date

2012-03-20, 1391/01/01

##### Expected recruitment end date

2013-03-20, 1391/12/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effects of massage on weight gain in premature infants at Imam Khomeini Hospital in 1389

##### Public title

Neonatal massage effect on weight gain

##### Purpose

Health service research

##### Inclusion/Exclusion criteria

Inclusion: All premature infants, written consent of the parents Exclusion: infants need to have surgery or respiratory support-infant have anomaly- congenital heart malformation-central nervous system dysfunction- NPO infants

##### Age

From **33 years** old to **36 years** old

##### Gender

Both

**Phase**  
N/A

**Groups that have been masked**  
No information

**Sample size**  
Target sample size: 34

**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

Maternal Fetal Neonatal Research Center, Tehran  
University of Medical Sciences, Tehran, Iran

##### Street address

Ethics committee of Tehran University of Medical  
Sciences, 6 th floor of Tehran University of Medical  
Sciences, ghods St., Keshavarz blv, Tehran, Iran

##### City

Tehran

##### Postal code

89-03-91-11478

#### Approval date

2010-11-09, 1389/08/18

#### Ethics committee reference number

89-03-91-11478

## Health conditions studied

### 1

#### Description of health condition studied

prematurity

#### ICD-10 code

p07.3

#### ICD-10 code description

other preterm infants

## Primary outcomes

### 1

#### Description

Weight gain of infants

#### Timepoint

Daily during the intervention

## Method of measurement

Balance

### 2

#### Description

amount of feeding

#### Timepoint

daily during the study

#### Method of measurement

A Questionnaire used infant the amount of milk in 24  
hours is a registered CC.

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention: massage, one hour after a meal, for 15  
days, 3 times daily for 15 minutes

#### Category

Other

### 2

#### Description

Control group: infantss who are not massaged.

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Valiasr Hospital

##### Full name of responsible person

Samaneh Sedghi

##### Street address

Vaiasr hospital, Imam Khomeini Hospital complexex,  
Keshavarz blv,14914, Tehran, Iran

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Maternal Fetal Neonatal Research Center, Tehran  
University of Medical Sciences

##### Full name of responsible person

Mamak Shariat

##### Street address

Vaiasr hospital, Imam Khomeini Hospital complexex,  
Keshavarz blv, Tehran, Iran

**City**  
Tehran

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**  
Yes

**Title of funding source**  
Maternal Fetal Neonatal Research Center, Tehran  
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**  
Maternal Fetal Neonatal Research Center, Tehran  
University of Medical Sciences, Tehran, Iran

**Full name of responsible person**  
Samaneh Sedghi

**Position**  
Researcher/ MD

**Other areas of specialty/work**

**Street address**  
Vaiastr hospital, Imam Khomeini Hospital complexex,  
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**City**  
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14197

**Phone**  
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samanesedghi@gmail.com

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Maternal Fetal Neonatal Research Center, Tehran  
University of Medical Sciences

**Full name of responsible person**  
Elahe Amini

**Position**

Professor/ Neonatologist

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Maternal Fetal Neonatal Research Center, Tehran  
University of Medical Sciences

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Samaneh Sedghi

**Position**  
Researcher/MD

**Other areas of specialty/work**

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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*