

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### Effect of foot massage on intensity of physiological edema of pregnancy

#### Protocol summary

##### Summary

This study is a single blind randomized clinical trial that has been performed to determine the effectiveness of foot massage on intensity of physiological oedema of pregnancy. the study population comprised all pregnant women referred to urban health- therapeutic centers and prenatal clinic of Amiralmomenin hospital of Kordkuy affiliated to Golestan University of Medical Sciences. according to statistical calculations to estimate number of samples, 120 pregnant women eligible for the study, were enrolled to study by easy sampling and divided by randomized allocation to the intervention or control group(60 persons in each group). duration of study was 5 days. in the first day of the study, the intensity of physiological oedema of foot by pressing of pointing and middle fingers on tibial bone was determined and measuring 3-point of circumference of the both feet included circumference of the ankles, circumference of the heels and circumference of the joint of between the toes and metatarsal bones by non-elastic tape were measured in both groups. then in each sample of intervention group, foot massage has been performed for 10 min by researcher and this intervention has been performed by researcher for 3 consecutive days in the homes of samples and in the fifth day, intervention in experimental group and measurements for the both groups, has been performed in research environment and in order to achieve the research objective, intensity of physiological oedema of pregnancy, before and after the intervention was been compared.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013012012198N1**

Registration date: **2013-03-08, 1391/12/18**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2013-03-08, 1391/12/18

##### Registrant information

###### Name

Mahdieh Kiani

###### Name of organization / entity

Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 17 3327 3594

###### Email address

kiani\_m@razi.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Tehran University of Medical Sciences.

##### Expected recruitment start date

2012-07-28, 1391/05/07

##### Expected recruitment end date

2012-11-10, 1391/08/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of foot massage on intensity of physiological edema of pregnancy

##### Public title

Effect of foot massage on physiological edema of pregnancy

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: age range 35-20 years; nulliparous

pregnant; single pregnancy; pregnancy 30 weeks or more; oedema in the feet to leg and limited to +/++; not having gestational hypertension and preeclampsia, not having any known systemic disease such as heart disease, lung, kidney, diabetes, thrombophlebitis, hypertension and ... and known skin disease such as eczema, skin dermatitis and ... and any visible damage or other obstacle in the massage area, lack of exercise as a professional; not receiving a foot massage two days before the start of the study. Exclusion criteria: the presence of gestational hypertension and preeclampsia; sensitivity to baby oil; not having consent to continue participating in the study.

**Age**

From **20 years** old to **35 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **120**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Single blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Tehran University of Medical Sciences

**Street address**

Tehran, Keshavarz blvd, edge of Qods street, central organization of University, Sixth floor

**City**

tehran

**Postal code****Approval date**

2012-07-17, 1391/04/27

**Ethics committee reference number**

765/ 130/91/5

**Health conditions studied****1****Description of health condition studied**

physiological oedema of pregnancy

**ICD-10 code**

o12.0

**ICD-10 code description**

Gestational oedema

**Primary outcomes****1****Description**

Intensity of physiological oedema of pregnancy

**Timepoint**

5 days after

**Method of measurement**

by pressing of pointing and middle fingers on tibial bone

**2****Description**

amount of physiological oedema of pregnancy

**Timepoint**

5 days after

**Method of measurement**

measure of circumference of the ankles, circumference of the heels and circumference of the joint between the toes and metatarsal bone by non-elastic tape

**Secondary outcomes**

empty

**Intervention groups****1****Description**

In the intervention group, the first day of the study, after completing the questionnaire and measuring the circumference of the ankles, circumference of the heels and circumference of the joint of between the toes and metatarsal bones, each foot massage has been performed for 10 min and for 3 consecutive days was performed in the homes of samples and in the fifth day, which is equal to the last day of the study, foot massage has been performed in research environment and measuring mentioned circumferences has been performed for feet. ( all of the above steps was performed by researcher.).

**Category**

Other

**2****Description**

In the control group, the first day of the study, after completing the questionnaire; measuring the circumference of the ankles, circumference of the heels and circumference of the joint of between the toes and metatarsal bones has been performed by researcher and

by non-elastic tape and during the study, there was no intervention, and in the fifth day, which is equal to the last day of the study; measuring mentioned circumferences has been performed by research assistant.

#### Category

N/A

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

urban health- therapeutic care center NO.1

###### Full name of responsible person

Maryam Joghataei

###### Street address

Kordkuy, Valiasr Street

###### City

Kordkuy

#### 2

##### Recruitment center

###### Name of recruitment center

urban health- therapeutic care center NO.2

###### Full name of responsible person

Dr Nastaran Soleymani

###### Street address

Kordkuy, Jangal Street

###### City

Kordkuy

#### 3

##### Recruitment center

###### Name of recruitment center

urban health- therapeutic care center( Former rural)

###### Full name of responsible person

Dr Ebrahim Mollaei

###### Street address

Kordkuy, Valaghuz

###### City

Kordkuy

#### 4

##### Recruitment center

###### Name of recruitment center

Prenatal clinic of Amiralмомenin hospital

###### Full name of responsible person

Mohadeseh Kiani

###### Street address

kordkuy, Jangal street, Imam Ali square

###### City

kordkuy

### Sponsors / Funding sources

#### 1

##### Sponsor

###### Name of organization / entity

Tehran University of Medical Sciences

###### Full name of responsible person

Dr Akbar Fotuhi

###### Street address

Tehran, Keshavarz Blvd, edge of Qods Street, Central organization of University, Sixth Floor

###### City

Tehran

##### Grant name

##### Grant code / Reference number

##### Is the source of funding the same sponsor organization/entity?

Yes

##### Title of funding source

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

Tehran University of Medical Sciences

###### Full name of responsible person

Mahdieh Kiani

###### Position

Master student of midwifery

###### Other areas of specialty/work

###### Street address

Tohid square, beginning of the Nosrat street, faculty of nursing and midwifery of Tehran University of Medical Sciences

###### City

Tehran

###### Postal code

###### Phone

+98 21 6692 7171

###### Fax

###### Email

kiani\_m@razi.tums.ac.ir

###### Web page address

### Person responsible for scientific inquiries

##### Contact

###### Name of organization / entity

Tehran University of Medical Sciences

###### Full name of responsible person

Fatemeh Rahimikian

**Position**

Msc of midwifery

**Other areas of specialty/work**

**Street address**

Tohid square, beginning of the Nosrat street, faculty of nursing and midwifery of Tehran University of Medical Sciences

**City**

Tehran

**Postal code**

**Phone**

+98 21 6692 7171

**Fax**

**Email**

f\_rahimikian@yahoo.com

**Web page address**

<http://www.tums.ac.ir/faculties/rahimikian>

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Mahdieh Kiani

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**Fax**

**Email**

kiani\_m@razi.tums.ac.ir

**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*