

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Comparing of the effect of massage and feet elevation 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 massage and feet elevation 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. 180 pregnant women eligible for the study, were enrolled to study by easy sampling and divided by randomized allocation to 3 groups, the massage, feet elevation and control group(60 persons in each group). 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 all three groups. Then in massage group, feet massage has been performed for 20 min while having the feet on the pillow with 20 centimeters in height and in feet elevation group, simply put of feet on the pillow with 20 centimeters in height was performed. Then measure the circumferences of the foot was performed again in all 3 groups. All these interventions were performed daily for 5 consecutive days. The physiological edema of pregnancy, before and after the 3 groups were compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013050512198N4**

Registration date: **2013-05-19, 1392/02/29**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-05-19, 1392/02/29

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

2013-06-22, 1392/04/01

Expected recruitment end date

2013-10-23, 1392/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing of the effect of massage and feet elevation on intensity of physiological edema of pregnancy

Public title

Comparing of the effect of massage and feet elevation 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: **180**

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/ۛ

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 massage 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 minutes , while having the feet for 20 minutes on the pillow with 20 centimeters in height and for 3 consecutive days foot massage was performed by researcher 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.

Category

Other

2

Description

In feet elevation 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, feet were for 20 minutes on the pillow with 20 centimeters in height and for 3 consecutive days feet elevation was performed by samples in their homes and in the fifth day, which is equal to the last day of the study, feet elevation has been performed in research environment and measuring mentioned circumferences has been performed for feet.

Category

Other

3

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 Amiralmomenin 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 TUMS

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

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

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