Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
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Iran (Islamic Republic of)
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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/د

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 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 Tehran University of Medical Sciences

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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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