Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

The effect of Modified Buerger Allen exercise on peripheral lower extremities edema during late pregnancy

Protocol summary

Study aim
The effect of modified Alan Burger exercises on peripheral inflammation of the lower extremities in late pregnancy

Design
Clinical trial with control group,on 10 pregnant women 30 to 40 weeks. In the first stage, screening is non-probability and easy based on inclusion and exclusion criterial. will be randomly assigned to research groups

Settings and conduct
will be referred to the health centers of Zahedan.Burger Allen training exercises are given in person,then complete demograghic and midwifery information questionnaire from the sample.the size of the heel,ankle,the joint between the metatarsals and the thumb will be measured using a tape measure and the foot volume with a volumetric and pain scale with a visual evaluation scale on days 1,5 and 10 of the study.

Participants/Inclusion and exclusion criteria
Inclusion criteria:age18 to 35,normal singleton pregnancy between 30 to 40 weeks,edema in the legs in the range of two plus, pain score 3 and more,body mass index in the normal range,normal condition of amniotic fluid and fetus,no history of infertility,Did not have any systemic disease, thrombophlebitis and hypertension,lack of absolute rest,no psychological problems,no drug addiction,limited pain in the sole of the foot and ankle, and pain from Other organs are not. Exclusion:Performing other exercises or other specific treatment to eliminate foot swelling during the study, unwillingness to perform exercises,premature delivery or any termination of pregnancy during the intervention,standing for a long time or having working conditions,sitting and standing for a long time,occur Problems such as fractures in the lower extremities,receiving medication or special diet to relieve pain and edema during the study

Intervention groups
Do Allen Burger exercises for 5 and 10 days

Main outcome variables
ankle,instep and joint between the toes and the metatarsal circumstance Foot volume pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200713048096N1**
Registration date: **2020-11-12, 1399/08/22**
Registration timing: **registered_while_recruiting**

Last update: **2020-11-12, 1399/08/22**
Update count: **0**

Registration date
2020-11-12, 1399/08/22

Registrant information

Name
Fatemeh Mollaelahi

Name of organization / entity
Tarbiat modares university

Country
Iran (Islamic Republic of)

Phone
+98 21 8288 3811

Email address
fatemehmollaelahi@modares.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-08-21, 1399/05/31

Expected recruitment end date
2021-08-22, 1400/05/31

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of Modified Buerger Allen exercise on peripheral lower extremities edema during late pregnancy

Public title
The effect of Buerger Allen exercise on lower extremities edema during late pregnancy
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria:
First and singleton pregnancies Age between 18 and 35 Normal pregnancy between 30 and 40 weeks Edam in the legs and feet up to 2 plus BMI in the normal range(Body mass index before pregnancy or in the first 6 weeks of pregnancy, can be adapted from the case of pregnant women and normal BMI 19.8 to 24 kg / m2) Normal weight gain during pregnancy according to the weight growth chart in the file Normal state of Amniotic Fluid and fetus No history of infertility Not suffering from any systemic disease such as heart, lung, diabetes, Thrombophlebitis and hypertension, skin diseases such as severe eczema Lack of absolute rest Absence of Preeclampsia and Eclampsia(according to the case) No psychological problems (according to the case) Not taking medication except pregnancy supplements(according to the case) No drug addiction(according to the case) The pain should be limited to the sole of the foot and ankle and not spread to other organs (according to the person)
Exclusion criteria:
Perform other exercises or other specific treatment to relieve foot edema during the study Reluctance to do exercises Premature delivery or any termination of pregnancy during the intervention Standing for a long time or having working conditions Sitting and standing for a long time Problems such as lower limb fractures Receive medication or a special diet to relieve pain and edema while studying Suffering from Preeclampsia in the intervention process Receive other methods of complementary medicine Reluctance to continue participating in the study
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **20**
Randomization (investigator's opinion)
Randomized
Randomization description
ple in the community from 1. This numbering will be done without observing any special order. Step 2: We will randomly select a number as the sampling source in the table of random numbers. Step 3: From the origin of nuns, we will consider rows with the number of nuns digits. Step 4: We will read the numbers of the selected rows in order. We will count each repeated number only once. The first selected number will be in the intervention group and the next number will be in the control group. Sampling will continue until the sample size is completed.
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
ethic committee of tarbiat modares university
Street address
Tehran - Jalal Al-Ahmad Highway ,Nasr Bridge
City
tehran
Province
Tehran
Postal code
14115-111
Approval date
2020-11-02, 1399/08/12
Ethics committee reference number
IR.MODARES.REC.1399.105

Health conditions studied

1

Description of health condition studied
Physiological edema of the lower extremities in late pregnancy
ICD-10 code
O12.0
ICD-10 code description
Gestational edema

Primary outcomes

1

Description
Percentage of pregnant women with lower extremity physiological edema

Timepoint
Measurement of leg edema at the beginning of the study and 5 and 10 days after the start of the intervention
Method of measurement
Measurement of ankle circumference, heel circumference and joint circumference between toes and metatarsal bone by tape measure and foot volume with volumeter

2

Description
Pain in the lower leg
Timepoint
Measurement of lower limb pain at the beginning of the study and 5 and 10 days after the start of the intervention
Method of measurement
Using a ten-point numerical scale(visual Analogue Scale) of pain and asking questions from the research unit

Secondary outcomes

1

Description
diet
Timepoint
Before and 5 and 10 days after the intervention
Method of measurement
Use of food frequency questionnaire

Intervention groups

1

Description
Intervention group: Intervention groups include a group that will perform Burger Allen exercises at home for 10 days after training. How to do the exercises is as follows: 1- In the flat position, lean to the left (LLT) with an angle of 30-45 degrees so that it is supported by protection and raise the legs at an angle of 45 to 90 degrees, Raise your legs on a chair or board for 1.5 to 3 minutes.2. Then sit down and hang your legs for 3 to 5 minutes to restore their color. Care will be taken not to put pressure on the knees. In fact, each leg should be bent and stretched and then placed in this position for 3 minutes. The legs should be completely pink. If the legs are blue or painful, lift them up and rest if necessary. 3. Then for 3 minutes horizontally at a 180 degree angle and quietly in a relaxed position in a flat to the left. Lie down (LLT) at an angle of 30-45 degrees and keep your feet warm with a blanket
Category
Treatment - Other

2

Description
Control group: The control group will receive routine prenatal care
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Hadi Health Center
Full name of responsible person
Maryam Liyaghat
Street address
moallem street,zahedan town
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Phone
+98 54 3341 3934
Email
public@zaums.ac.ir

2

Recruitment center
Name of recruitment center
Emam Javad Health Center
Full name of responsible person
Mahbube Gholami
Street address
Razi street,zahedan Town
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Phone
+98 54 3344 1898
Email
public@zaums.ac.ir

3

Recruitment center
Name of recruitment center
Mosa Ebne Jafar Helth Center
Full name of responsible person
Hajar Abbasi
Street address
Mirzaye Shirazi street,zahedan town
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Phone
+98 54 3328 3941

Email
public@zaums.ac.ir

4

Recruitment center
Name of recruitment center
Hejrat Health center
Full name of responsible person
Nasrin Mahmoodi
Street address
Daneshgah 31 Street,Zahedan Town
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Phone
+98 54 3344 0059
Email
public@zaums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
The University of Tarbiat modare
Full name of responsible person
Shadab Sahali
Street address
Jalal Al Ahmad High way,university of tarbiat modare,Tehran,Iran
City
Tehran
Province
Tehran
Postal code
14115111
Phone
+98 21 8828 1183
Email
shadab.shahali@modares.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
The University of Tarbiat modare
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Trabiat Modares University
Full name of responsible person
Shadab Shahali
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
Street address
Jalal Al-Ahmad Highway, Faculty of Medical Sciences, Tarbiat Modares University, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
14115111
Phone
+98 21 8828 1183
Email
shadab.shahali@modares.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tarbiat modares University
Full name of responsible person
Shadab Shahali
Position
Assistant Proofessor
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
Street address
Jalal Al-Ahmad Highway, Faculty of Medical Sciences, Tarbiat Modares University, Tehran, Iran
City
Tehran
Province
Sistan-va-Balouchestan
Postal code
14115111
Phone
+98 21 8828 1183
Email
Shadab.Shahali@modares.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Tarbiat Modares University

Full name of responsible person
Fatemeh Mollaelahi
Position
Masters student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
daneshjoo 44 street ,zahedan town
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816858346
Phone
+98 54 3344 9748
Email
fatemehmollaelahi@modares.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
no more information
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Part of the data on the primary and secondary outcomes will be shared.
When the data will become available and for how long
year of 1400
To whom data/document is available
researchers
Under which criteria data/document could be used
Carrying out research work through a written request from the responsible author
From where data/document is obtainable
Corresponding Author, Tarbiat Modares University, Faculty of Medical Sciences, Department of Midwifery and Reproductive Health
What processes are involved for a request to access data/document
After sending a written request to the responsible author, the request will be sent to the research unit of Tarbiat Modares University and in case of non-compliance with the rules, the analysis data will be provided to the researcher.
Comments