

# 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 criteria. 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 demographic 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: age 18 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 circumference  
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 Edema 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 / m<sup>2</sup>) 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**

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#### **Province**

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#### **Postal code**

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#### **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

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Academic

#### 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**  
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#### **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**

#### **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**  
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**Province**  
Tehran  
**Postal code**  
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**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 Professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
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Jalal Al-Ahmad Highway, Faculty of Medical Sciences,  
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+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**