

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The effect of exercise training with and without physiotherapy on the prevention of deep vein thrombosis in pregnant women requires emergency cardiac surgery.

Protocol summary

Study aim

The effect of exercise training with and without physiotherapy on the prevention of deep vein thrombosis in pregnant women requires emergency cardiac surgery

Design

This study is a randomized clinical trial with no control group with parallel groups, which is a data analyzer compared to blind grouping.

Settings and conduct

Participants in cardiac hospitals across Iran will be included in the study and will receive intervention after being randomly allocated to the two groups. Intervention in Group 1 will be such that each person performs a simple exercise within three days prior to surgery in the morning, then six hours later, the physiotherapist will receive tensile physical therapy in the organs. The second group will do light exercise for one hour three times daily (once a day) three days before surgery. The data analyst will be unaware of the type of grouping and is blind in the study.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 1- Pregnancy 2- Need for emergency heart surgery Exclusion Criteria: 1- One foot stomach 2. Inability to walk 3. Inability to exercise

Intervention groups

Participants will be randomly divided into two groups; participants in the first group (exercise + physiotherapy) will receive the intervention the day before the heart surgery. Participants in the second group (exercise) will perform three exercises three days before the surgery.

Main outcome variables

Deep vein thrombosis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190325043107N6**

Registration date: **2019-07-18, 1398/04/27**

Registration timing: **prospective**

Last update: **2019-07-18, 1398/04/27**

Update count: **0**

Registration date

2019-07-18, 1398/04/27

Registrant information

Name

Mehdi Khanbabayi Gol

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3334 7054

Email address

khanbabayimehdi69@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-21, 1398/04/30

Expected recruitment end date

2019-09-21, 1398/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of exercise training with and without physiotherapy on the prevention of deep vein thrombosis

in pregnant women requires emergency cardiac surgery.

Public title

Prevention of DVT in pregnant women requires emergency cardiac surgery

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Pregnancy Needed Emergency Cardiac Surgery

Exclusion criteria:

Amputation of one of the legs Inability to walk Inability to do sports

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Not randomized

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

Single blinded

Blinding description

The participants in the study will be divided into groups, and each person's information will be recorded on a special form, and then the data will be delivered to the analyst. The analyst is not aware of the type of grouping and which form the transcript belongs to, and is blind in the study.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Tabriz University of Medical Sciences

Street address

Imam Reza Hospital, Azadi Ave

City

Tabriz

Province

East Azarbaijan

Postal code

5165665631

Approval date

2019-03-11, 1397/12/20

Ethics committee reference number

IR.TBZMED.REC.1397.1059

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

Deep vein thrombosis

ICD-10 code

O22.3

ICD-10 code description

Deep phlebothrombosis in pregnancy

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

Deep vein thrombosis

Timepoint

Daily

Method of measurement

Blood tests

Secondary outcomes

empty

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

Intervention group: The group will receive intervention within three days before surgery. In the morning, they will do light exercise daily for an hour, and six hours later they will receive physiotherapy in the organs by a physiotherapist.

Category

Prevention

2**Description**

Control group: The group will do light exercise for three hours before surgery and daily for one hour at the morning.

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Madani Hospital

Full name of responsible person

Mehdi Khanbabayi Gol

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2

Recruitment center

Name of recruitment center
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz University of Medical Sciences

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
Tabriz University of Medical Sciences
Full name of responsible person
Mehdi Khanbabayi Gol
Position
MSc in Nursing Education
Latest degree
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Latest degree

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Other areas of specialty/work

Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available