Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 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

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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

Street address
Azadi Ave, Shahid Madani Hospital
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2

Recruitment center
Name of recruitment center
Shaeed Rajayi
Full name of responsible person
Mehdi Khanbabayi Gol
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Valiasr Ave Niayesh Intersection , Shaheed Rajaie Cardiovascular Medical and Research Center
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mkhanbabayi@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Abolghasem Jouyban
Street address
Imam Reza Hospital, Azadi Ave
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Tabriz
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Email
Ajouyban@hotmail.com
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
Master
Other areas of specialty/work
Nursery
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Person responsible for updating data

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Latest degree

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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