

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Evaluation of the effect of pentoxifylline on the prevention of erythrocyte lysis in cardiac surgery patients undergoing cardiopulmonary bypass

Protocol summary

Study aim

Determining the effect of pentoxifylline on increasing the flexibility of red blood cells in patients undergoing cardiopulmonary bypass

Design

Due to the fact that there are no exact studies and the necessary information to estimate the sample size. Individuals in a pilot study consisting of 15 people in each group and using the information of this pilot study, the sample size will be estimated and announced.

Settings and conduct

The statistical population is all patients who will undergo open heart surgery in Kosar Hospital in Semnan

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients undergoing open heart surgery, absence of vascular disease, patients with no hemoglobinopathy or disorder that causes erythrocyte lysis, patients with no contraindications to pentoxifylline. To be.

Intervention groups

Patients enrolled in the study will be divided into two groups using a table of random numbers based on a computer random sequence. The first group will take 400 mg of pentoxifylline and the second group will take a placebo every 8 hours for three days before surgery.

Main outcome variables

Determining the effect of pentoxifylline on peripheral blood smear changes after surgery, Determining the effect of pentoxifylline on hemoglobinuria after surgery, Determining the effect of pentoxifylline on hemoglobin after surgery, Determining the effect of pentoxifylline on hematuria after surgery, Determining the effect of pentoxifylline on serum bilirubin after surgery, Determining the effect of pentoxifylline on the percentage of reticulocytes after surgery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210420051018N1**

Registration date: **2021-11-15, 1400/08/24**

Registration timing: **prospective**

Last update: **2021-11-15, 1400/08/24**

Update count: **0**

Registration date

2021-11-15, 1400/08/24

Registrant information

Name

mohammad forozeshfard

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3344 1022

Email address

mff45@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-30, 1400/09/09

Expected recruitment end date

2022-04-29, 1401/02/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of pentoxifylline on the prevention of erythrocyte lysis in cardiac surgery patients undergoing cardiopulmonary bypass

Public title

Evaluation of the effect of pentoxifylline on the prevention of erythrocyte lysis in cardiac surgery patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients undergoing open heart surgery
Absence of blood vessel disease
Patients who do not have hemoglobinopathy or a disorder that causes red blood cell lysis
Patients who do not have a contraindication to pentoxifylline.

Exclusion criteria:

Patients with renal and hepatic insufficiency

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: 15

Randomization (investigator's opinion)

Randomized

Randomization description

The study will be conducted as a clinical trial with an equivalent group and with before and after measurements. Using a table of random numbers based on computer random sequence, they will be divided into two groups. They will take it every 8 hours before the surgery

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, after selecting the sample and describing the objectives of the study, participants (patients) will be randomly divided into two groups. A separate code is defined for each person and the participants will be given the main drug and placebo without knowing which group they are in. Blinding will inform.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Semnan University of Medical

Sciences

Street address

Kowsar educational and research center, Golestan town.

City

Semnan

Province

Semnan

Postal code

35198-99951

Approval date

2021-07-26, 1400/05/04

Ethics committee reference number

IR.SEMUMS.REC.1400.104

Health conditions studied

1

Description of health condition studied

All patients undergo open heart surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Determination of the effect of pentoxifylline on erythrocyte flexibility in patients undergoing cardiopulmonary bypass

Timepoint

400 mg pentoxifylline tablets every 8 hours for three days before heart surgery

Method of measurement

check list

2

Description

Determining the effect of pentoxifylline on peripheral blood smear changes after surgery

Timepoint

Before surgery and 24 hours after surgery

Method of measurement

Laboratory tests

3

Description

Determining the effect of pentoxifylline on hemoglobinuria after surgery

Timepoint

Before surgery and 24 hours after surgery

Method of measurement

Laboratory tests

4

Description

Determining the effect of pentoxifylline on serum

bilirubin after surgery
Timepoint
Before surgery and 24 hours after surgery
Method of measurement
Laboratory tests

5

Description
Determining the effect of pentoxifylline on the percentage of reticulocytes after surgery
Timepoint
Before surgery and 24 hours and 48 hours after surgery
Method of measurement
Laboratory tests

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Candidates who are candidates for cardiopulmonary bypass will take 400 mg pentoxifylline tablets made by Hakim Pharmaceutical Company every 8 hours for three days before surgery.
Category
Treatment - Drugs

2

Description
Control group: Candidates who will be candidates for cardiopulmonary bypass will take a placebo every 8 hours from the three days before surgery, much like the drug studied by Hakim Pharmaceutical Company.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kosar Hospital, Semnan
Full name of responsible person
Mohammad Foroozeh Fard
Street address
Kowsar educational and research center,Golestan town.
City
Semnan
Province
Semnan
Postal code
35198-99951
Phone
+98 23 3343 7837

Email
mff45@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Mohammad Foroozeh Fard
Street address
Kowsar educational, research and treatment center,Golestan town.
City
Semnan
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Semnan
Postal code
35198-99951
Phone
+98 23 3343 7837
Email
mff45@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Semnan 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
Semnan University of Medical Sciences
Full name of responsible person
Mohammad Foroozeh Fard
Position
full Profesor
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
Street address
Kowsar educational, research and treatment center,Golestan town.
City
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Person responsible for scientific inquiries

Contact

Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Mohammad Foroozeh Fard
Position
full Profesor
Latest degree
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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Position
full Profesor
Latest degree
Subspecialist
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data is potentially shareable after unidentified individuals

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

The data of this research will be available to all researchers working in academic and scientific institutions

Under which criteria data/document could be used

They can request this email for information :mff45@yahoo.com

From where data/document is obtainable

They can request this email for information :mff45@yahoo.com

What processes are involved for a request to access data/document

They can request this email for information :mff45@yahoo.com

Comments