Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 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
n 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

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35198-99951

Phone

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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

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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

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

Semnan

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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
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Subspecialist
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Person responsible for updating data

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Full name of responsible person
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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