Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

The efficiency and effectiveness of the ACT, ROTEM protocol for neutralizingprotamine heparin in adult patients with open heart surgery (CABG) at ShahidRajaee Cardiovascular Research and Treatment Center

Protocol summary

Study aim

The purpose of this study was to investigate the effect on the amount of bleeding in patients and the relationship between ROTEM and protamine overdose

Design

The clinical trial has two groups of intervention and control, community-based, as well as two parallel groups, one-blind blind

Settings and conduct

Considering that one of the important aspects during the open heart surgery is the process of control Coagulation of the patient in order to prevent blood clotting during surgery, and one of the most important Our best criteria for deciding whether or not to start a patient's surgery During surgery, one of the issues that affects the quality of the operation is the issue of hemorrhage, and this process should be monitored. The site is the centerpiece of Shahid Rajaee Cardiology, Research and Therapy Center. The method of this study is to examine the intervention and control groups during the operation. In the intervention group, the protocol is seeking to achieve the minimum amount of bleeding and complications due to inhibition of the coagulation mechanisms of the patient.

Participants/Inclusion and exclusion criteria

Patients who undergo surgery for the first time and have not received anticoagulant drugs are among our entrants. Patients undergoing surgery for the second time or more, or coagulation disorders or receiving anticoagulants, are excluded from our study.

Intervention groups

In the intervention group, by analyzing the protocol for the neutralization of patient's coagulation pathways, we seek to reduce unwanted complications as well as unwanted bleeding during and after surgery so that we can have less costly surgery and fewer complications.

Main outcome variables

Check the amount of bleeding;Check the blood cell pack consumption; Assessing the length of hospitalization in the ICU

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180719040524N1**
Registration date: **2019-07-23, 1398/05/01**
Registration timing: **retrospective**

Last update: **2019-07-23, 1398/05/01**
Update count: **0**

Registration date

2019-07-23, 1398/05/01

Registrant information

Name

Ali Ghaffari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6656 7510

Email address

aliasghaffari@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-23, 1397/08/01

Expected recruitment end date

2019-02-20, 1397/12/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The efficiency and effectiveness of the ACT, ROTEM protocol for neutralizingprotamine heparin in adult patients with open heart surgery (CABG) at ShahidRajaee Cardiovascular Research and Treatment Center

Public title
The efficacy of neutralizing heparin by prothamine in cardiac open heart surgery
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria:
Patients who do not have an anticoagulant drug Patients undergoing surgery for the first time
Exclusion criteria:
Patients with a history of heart surgery Patients with coagulation disorders Patients with liver and kidney failure
Age
No age limit
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Patients undergoing surgery are divided into two intervention and control groups that are divided into the knowledge of the medical staff as well as the patients between the two groups, so that the patients do not know which group they are divided into and after entering the operating room.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee, Faculty of Pharmacy and Pharmaceutical Sciences, Islamic Azad University of Medica
Street address
No.24;38 street;shahr ara street
City
tehran
Province
Tehran
Postal code
144574429
Approval date
2018-11-06, 1397/08/15
Ethics committee reference number
IR.IAU.PS.REC.1397.294

Health conditions studied

1

Description of health condition studied
Heart disease
ICD-10 code
I70
ICD-10 code description
Atherosclerosis

Primary outcomes

1

Description
To investigate more precisely the blood factors and the results of neutralizing the effects of anticoagulant drugs used during surgery, we use the ROTEM device.
Timepoint
At the end of the operation, if necessary, an observer will be used
Method of measurement
By ROTEM

2

Description
Our primary variable is the patient's activated clotting time (ACT)
Timepoint
ACT is taken from the beginning of the surgery every hour and ACT is taken at the end of the operation, after neutralizing the effect of heparin ACT.
Method of measurement
Measured by ACT

Secondary outcomes

empty

Intervention groups

1

Description

Our intervention group on the day of operation after taking the anesthetic is taken from the ACT patient at the start of the procedure, and then 3mg / kg heparin is given to prepare the patient for the pump to go. The ACT is acceptable to go to the 420-480sec pump. In order to ensure that this number is taken again, ACT is taken. The pump is also impregnated with 100 milligrams of heparin to prevent the possibility of blood coagulation in the pump ducts. After the patient goes to the pump half an hour later, we take another ACT. And then, depending on the duration of the action, if the discretion and necessity of every hour, an ACT is taken from the patient. At the end of the operation, when you want Let's warm the patient and bring her body temperature to 36.5 degrees from the ROTEM patient as well as the ACT before the pump is turned off. When the patient is transferred to the ICU (ACT), ACT is taken and one hour later if We look at the bleeding from the ROTEM patient in order to investigate the underlying cause. According to this protocol, we try to achieve the optimal dose of heparin and protamine and the dose of the two for the patient from the amount of unwanted bleeding at the end of the patient. Practicing and wasteful use of industrial products.

Category

Treatment - Surgery

2

Description

Control group: Our control group is selected on the basis of anesthesiologists' and epidemiologist's discretion and placed on the routine of the operating room under anesthesia and attached to the pump.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Rajaie Heart Hospital
Full name of responsible person
Ali Ghaffari
Street address
End Of Hashemi Rafsanjani Highway
City
Tehran
Province
Tehran
Postal code
1995614331
Phone
+98 21 23921
Fax
+98 21 2204 2026
Email
aliasghaffari@gmail.com
Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Rajaie Heart Hospital
Full name of responsible person
Dr. Hooman Bakhshandeh
Street address
End of Hashemi Rafsanjani Highway
City
Tehran
Province
Tehran
Postal code
1995614331
Phone
+98 21 23921
Email
aliasghaffari@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Rajaie Heart Hospital
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
Islamic Azad University
Full name of responsible person
Seyed Mostafa Alavi
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
Street address
Shahid Rajaie Heart Hospital ;Hashemi Rafsanjani Hwy
City

Tehran

Province
Tehran

Postal code
1115119969

Phone
+98 21 23921

Email
aliasghaffari@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Seyed Mostafa Alavi

Position
Professor

Latest degree
Subspecialist

Other areas of specialty/work
Anesthesiology

Street address
Rajaie Heart Hospital;Hashemi Rafsanjani Hwy

City
Tehran

Province
Tehran

Postal code
1115119969

Phone
+98 21 23921

Email
aliasghaffari@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Ali Ghaffari

Position
Student

Latest degree
Medical doctor

Other areas of specialty/work
Medical Pharmacy

Street address
No. 24;38 street;Shahr Ara Street

City
Tehran

Province
Tehran

Postal code
144574429

Phone
+98 21088242777

Email
aliasghaffari@gmail.com

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

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Part of the extracted data from patient analyzes after unidentifiable patients for sharing is possible.

When the data will become available and for how long
The publication time of the documentation is considered 3 months after the publication of the results

To whom data/document is available
Access to data is only possible for researchers and professors working in health centers.

Under which criteria data/document could be used
Only a review request for use in future investigations will be allowed.

From where data/document is obtainable
1-email: aliasghaffari@gmail.com 2-Mobile: 09126718543; Ali Ghaffari

What processes are involved for a request to access data/document
Upon request, the applicant receives documentation about 3 months from the date of receipt of the documentation

Comments