

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Investigating the effect of systemic anticoagulants on the out come of primary repairing arterial injuries due to penetrating trauma of the upper limb

Protocol summary

Study aim

Evaluation of the effect of systemic anticoagulants on anastomotic blood flow after initial repair of arterial injuries in patients with penetrating upper limb arterial trauma

Design

Randomized clinical trial, with control group, with parallel groups, without blinding, phase 3 on 118 patients. Blocking method was used for randomization using Randomization.com online software.

Settings and conduct

A randomized clinical trial study without blindness that will be performed after approval by the ethics committee of Arak University of Medical Sciences in Valiasr Hospital.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age less than 30 years, upper extremity arterial injury requiring surgical repair.
Exclusion criteria: Simultaneous injury to other parts of the body, concurrent nerve damage that causes sensory or motor disturbances on examination, underlying vascular disease

Intervention groups

Intervention group: Patients receive heparin during treatment (5000 units as intravenous bolus). They then receive intravenous infusion of heparin maintenance therapy (18 units per kilogram per hour) within 24 hours after surgery. Control group: Patients receive heparin during treatment (5000 units as intravenous bolus). They will then receive standard treatment.

Main outcome variables

Upper extremity blood supply

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190717044255N3**

Registration date: **2021-11-29, 1400/09/08**

Registration timing: **prospective**

Last update: **2021-11-29, 1400/09/08**

Update count: **0**

Registration date

2021-11-29, 1400/09/08

Registrant information

Name

Ali Azizi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-22, 1400/10/01

Expected recruitment end date

2022-02-19, 1400/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of systemic anticoagulants on the out come of primary repairing arterial injuries due to penetrating trauma of the upper limb

Public title

The effect of systemic anticoagulants in repairing penetrating upper limb arterial trauma

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age less than 30 years Upper extremity vascular injury that requires surgical repair

Exclusion criteria:

Existence of multiple injuries in other parts of the body
Existence of nerve damage associated with impaired sensory and motor examination Underlying vascular disorders

Age

From **18 years** old to **30 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **116**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization in this study will be done using block randomization method. In this way, patients will be divided into 20 blocks of 6 by Randomization.com online software. Then, in order to hide 20 envelopes with aluminum wrappers (in order to obscure the contents of the envelopes), prepare and create each of random sequences. It is registered on a card and the cards are placed in the envelopes of the order, respectively. In order to maintain a random sequence, the envelopes are numbered in the same way on the outer surface. Finally, the lids of the letter envelopes are glued and placed inside a box, respectively. At the beginning of the registration of participants, based on the order of entry of eligible participants into the study, one of the envelopes of the letter is opened in order and the assigned group of the participant is revealed.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee**

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Basij sq., Sardasht Town

City

Arak

Province

Markazi

Postal code

3848176341

Approval date

2021-10-25, 1400/08/03

Ethics committee reference number

IR.ARAKMU.REC.1400.191

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

Arterial trauma

ICD-10 code

I23.6

ICD-10 code description**Primary outcomes****1****Description**

Arterial blood supply

Timepoint

6 hours after surgery, 24 hours after surgery, at discharge, one week after discharge

Method of measurement

Based on clinical examination criteria for limb color, end pulses, sensation and movement, and capillary filling

Secondary outcomes

empty

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

Fifty-eight patients will receive a 5,000-unit intravenous heparin treatment during surgery (Chimidar, Iran) and then receive standard anticoagulant therapy after surgery.

Category

Treatment - Drugs

2**Description**

Intervention group: During surgery, 58 patients received 5,000 units of heparin (Chimidar, Iran) intravenous bolus treatment for once. Then, within 24 hours after surgery, they receive heparin maintenance treatment (Chimidar, Iran) at a rate of 18 units per kilogram per

hour as an intravenous infusion.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital

Full name of responsible person

Farshad Fereydoon Rajabi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Farshad Fereydoon Rajabi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

Contact

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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