Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of ischemic preconditioning on IL-10, hemodynamic and pulmonary indices after deflation of surgical torniquet

Protocol summary

Summary

The patients are randomly allocated to intervention and placebo groups. In placebo group, torniquet in placed on the contralateral thigh but not inflated. In the intervention group, torniquet is inflated up to 20 mmHg higher than systolic blood pressure for 5 minutes. This procedure is repeated for three times with five min rest between inflations. IL-10 is measured after torniquet deflation in both groups. Outcomes measures include blood pressure, pulse rate, pulse oximetry and ABG parameters. These data are recorded before torniquet inflation, and after inflation in 10 min intervals up to 30 minutes. The duration of torniquet inflation and surgery, blood loss and maintenance fluids are also recorded by the anesthesia resident.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201304055026N2**
Registration date: **2013-04-12, 1392/01/23**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2013-04-12, 1392/01/23

Registrant information

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Rasul Akram hospital, Tehran University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source
Tehran University of Medical Sciences (Thesis and research project budget)

Expected recruitment start date

2013-04-21, 1392/02/01

Expected recruitment end date

2014-06-22, 1393/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of ischemic preconditioning on IL-10, hemodynamic and pulmonary indices after deflation of surgical torniquet

Public title

Reducing the cardiopulmonary complications of orthopedic surgeries

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: elective cases of lower extremity fractures candidate of surgery with torniquet inflation more than 1 hr and ASA physical status I-III. Exclusion criteria: head/chest trauma; contra lateral fracture; deep sedation required (more than 1 mg midazolam); inadequate level of spinal anesthesia; High spinal anesthesia and addict patients.

Age

From **18 years** old to **149 years** old

Gender

Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tehran University of Medical Sciences
Street address
Hemmat Blv.
City
Tehran
Postal code
Approval date
2013-03-10, 1391/12/20
Ethics committee reference number
91-04-30-20020

Health conditions studied

1

Description of health condition studied
Hypotension
ICD-10 code
I98.8
ICD-10 code description
Other specified disorders of circulatory system in diseases classified elsewhere

2

Description of health condition studied
hypoxemia
ICD-10 code
ICD-10 code description

3

Description of health condition studied
Acute lung injury
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Blood pressure
Timepoint
Before cuff inflation and after cuff deflation in 10 min intervals up to 30 min
Method of measurement
mmHg

2

Description
Heart rate
Timepoint
Before cuff inflation and after cuff deflation in 10 min intervals up to 30 min
Method of measurement
ECG monitoring

3

Description
Arterial oxygen saturation
Timepoint
Before cuff inflation and after cuff deflation in 10 min intervals up to 30 min
Method of measurement
Pulse oximetry

Secondary outcomes

1

Description
IL-10
Timepoint
Before cuff inflation and after cuff deflation
Method of measurement
ELISA

Intervention groups

1

Description
In the intervention group, torniquet is inflated up to 20 mmHg higher than systolic blood pressure for 5 minutes. This procedure is repeated for three times with five min rest between inflations.
Category
Treatment - Other

2

Description

In placebo group, torniquet in placed on the contralateral thigh but not inflated.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul Akram Medical Center

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Scienes

Full name of responsible person

Akbar Fotouhi

Street address

6th floor, Tehran University of medical sciences, Ghods Ave., Keshavarz Blv.

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran University of Medical Scienes

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Fatemeh Jamshidi

Position

MD, Resident of anesthesiology

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Assistant professor of Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty