

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of Amino Acid Infusion preventive effect on Hypothermia during Spinal Anesthesia for Hip Arthroplasty

Protocol summary

Study aim

To survive of the effect of Intravenous amino acid infusion prevents hypothermia during surgery under spinal anesthesia on reducing the degree of hypothermia and postoperative shivering

Design

This is a randomized, controlled, double-blinded clinical trial that 36 adults undergoing Hip Arthroplasty were randomly assigned into two groups of 18 each.

Settings and conduct

patients who were scheduled for elective primary hip arthroplasty, in Imam Reza Hospital, Mashhad, Iran were entered in this study.

Participants/Inclusion and exclusion criteria

candidate to hip arthroplasty during Spinal Anesthesia

Intervention groups

Intervention group: Before induction, the patients received 150 cc per hour of 10% amino acid. Control group: Ringer serum 150 cc per hour before induction.

Main outcome variables

The dermatome level of blockade

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170429033680N5**

Registration date: **2018-01-30, 1396/11/10**

Registration timing: **retrospective**

Last update: **2018-01-30, 1396/11/10**

Update count: **0**

Registration date

2018-01-30, 1396/11/10

Registrant information

Name

Farideh Golhasani

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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golhasanif1@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2012-09-19, 1391/06/29

Expected recruitment end date

2015-04-29, 1394/02/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Amino Acid Infusion preventive effect on Hypothermia during Spinal Anesthesia for Hip Arthroplasty

Public title

Evaluation of Amino Acid Infusion preventive effect on Hypothermia during Spinal Anesthesia for Hip Arthroplasty

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Candidated to hip arthroplasty Undergoing spinal anesthesia

Exclusion criteria:

Primary coagulation disorder Diabetic Secondary hip

arthroplasty consuming of NSAIDS drugs sensitive to amino acids Consuming Atropin before surgery

Age

From **16 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **36**

Actual sample size reached: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was done by simple methods, the tools used in randomization was table of random numbers

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the investigator and patients are unaware from the type of drug. Blinding was done by closed envelopes.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical sciences

Street address

Mashhad University of Medical Sciences; International Offic Administration Center(Qoreishi Building) ; Daneshgah St.,

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944-

Approval date

2010-09-29, 1389/07/07

Ethics committee reference number

89282

Health conditions studied

1

Description of health condition studied

Spinal Anesthesia

ICD-10 code

F44.6

ICD-10 code description

Conversion disorder with sensory symptom or deficit

Primary outcomes

1

Description

Heart rate

Timepoint

during surgery

Method of measurement

Using an electrocardiogram or ECG device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The amino acid(10%) of an hour before anesthesia starts at 240 kj / hr and continue until the end of surgery.

Category

Prevention

2

Description

Control group: Ringer Serum Injection

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital, Mashhad University of Medical Sciences

Full name of responsible person

Arash Peivandi Yazdi

Street address

Department of Anesthesiology, Imam Reza (AS) Hospital, Taghiabad Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohsen Tafaghodi

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Mashhad University of Medical Sciences; International
Office Administration Center (Qoreishi Building) ;
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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Mahsa Rajaei

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Full name of responsible person

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Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mahsa Rajaei

Position

Resident

Latest degree

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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
proposal

When the data will become available and for how long

1 month

To whom data/document is available

Email

Under which criteria data/document could be used

Researcers of University

From where data/document is obtainable

sent an Email to Rajaeim931@mums.ac.ir

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

on time

Comments