

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 2026

### Comparative induction of controlled hypotension by Acupuncture point DU20 electrostimulation and Remifentanil in lumbar laminectomy

#### Protocol summary

##### Summary

This randomized clinical trial study aims to compare the induction of controlled hypotension by acupuncture point DU.20 electro stimulation and Remifentanil in the patients undergoing laminectomy. General anesthesia is induced in all patients using Fentanyl (2 mcg/kg), Propofol (2mg/kg) and Atracurium (0.5 mg/kg) and is maintained using Isoflurane (BIS 40-60). Then the patients are divided into two groups. In the control group, controlled hypotension is induced using Remifentanil added to the other anesthesia drugs and in the case group, electro stimulation of acupoint DU.20 is used instead of Remifentanil. In both groups, in spite of using these methods, if mean arterial pressure (MAP) is above 70 mmHg, Nitroglycerin will be added to the others. In the course of surgery, the hemodynamic variables, bloodlessness scale of surgical field and intraoperative blood loss are recorded and compared between both groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201509213379N3**

Registration date: **2015-10-13, 1394/07/21**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-10-13, 1394/07/21

##### Registrant information

##### Name

Mehdi Ghaemi

##### Name of organization / entity

Zanjan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 24 1728 9915

##### Email address

mahiar@zums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice- chancellery for Research of Zanjan University of Medical Sciences

##### Expected recruitment start date

2015-10-02, 1394/07/10

##### Expected recruitment end date

2016-03-19, 1394/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparative induction of controlled hypotension by Acupuncture point DU20 electrostimulation and Remifentanil in lumbar laminectomy

##### Public title

The effect of Acupuncture on reduction of blood pressure

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: The patients aged between 20-60 years old and classified as ASA I and ASA II who are candidated for elective laminectomy Exclusion criteria: The patients who have history of Asthma, cardiovascular, liver and renal diseases and take anticoagulant and aspirin

##### Age

From **20 years** old to **60 years** old

##### Gender

Both

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 54

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Single 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 Zanjan University of Medical Sciences

##### Street address

Azadi Square

##### City

Zanjan

##### Postal code

4515613113

#### Approval date

2015-09-01, 1394/06/10

#### Ethics committee reference number

ZUMS.REC.1394.136

## Health conditions studied

### 1

#### Description of health condition studied

Induced Hypotension

#### ICD-10 code

195.2

#### ICD-10 code description

Hypotension due to drugs

## Primary outcomes

### 1

#### Description

reduction of mean arterial pressure(MAP)

#### Timepoint

every ten minutes after intervention

## Method of measurement

mmHg by blood pressure monitor

## Secondary outcomes

### 1

#### Description

bloodlessness quality of surgical field

#### Timepoint

every 30 minutes after intervention

#### Method of measurement

according to scale adapted from Dolman et al.

## Intervention groups

### 1

#### Description

Electrostimulation of Acupoint Du20

#### Category

Treatment - Other

### 2

#### Description

infusion of Remifentanil 100 mcg/kg/min

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Mousavi Hospital

##### Full name of responsible person

Mehdi Ghaemi

##### Street address

No.10-5,Kosar14 st., Shahrak Niksazan

##### City

Zanjan

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

vice-chancellery for research of Zanjan University of Medical Sciences

##### Full name of responsible person

Mrs. Feizy

##### Street address

Azadi square

##### City

Zanjan

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor

**organization/entity?**

Yes

**Title of funding source**

vice-chancellery for research of Zanjan University of Medical Sciences

**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**

Zanjan University of Medical Sciences

**Full name of responsible person**

Dr. Mehdi Ghaemi

**Position**

Anesthesiologist

**Other areas of specialty/work****Street address**

No.10-5, Kosar 14 st., Shahrak Niksazan

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**Web page address****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*