

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### Evaluating the Effect of Dexmedetomidine Infusion on Gene Expression of Inflammatory Cytokines & Lymphocyte T CD4 + Transcription Factors in Elective Abdominal Aortic Aneurysm Repair

#### Protocol summary

##### Study aim

The aim of this study was to evaluate the effect of Dexmedetomidine infusion on the expression of inflammatory cytokines and transcription factors of T lymphocytes during elective surgery of abdominal aortic aneurysm.

##### Design

Two arm parallel group randomised trial with blinded postoperative care and outcome assessment,

##### Settings and conduct

Shohada Tajrish Hospital

##### Participants/Inclusion and exclusion criteria

Entry into the study of candidates for elective abdominal aortic surgery and the rate of emergency exit surgery and any unpredictable conditions during surgery

##### Intervention groups

The subjects undergoing anesthesia induction with doses of 0.3mcg / kg / hour doses of doxedemotomidine until aortic clamp and the control group did not receive doxedetomidine infusion

##### Main outcome variables

The relative level of mRNA IL-6; The relative level of TNF- $\alpha$  mRNA; Relative level of IL-1 mRNA; Relative level of T-beT mRNA; Relative level of ROR-T mRNA; Relative level of GATA-3 mRNA; Relative level of FOXP3 mRNA

#### General information

##### Reason for update

##### Acronym

-

##### IRCT registration information

IRCT registration number: **IRCT20190121042444N1**

Registration date: **2019-06-13, 1398/03/23**

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

Last update: **2019-06-13, 1398/03/23**

Update count: **0**

##### Registration date

2019-06-13, 1398/03/23

##### Registrant information

###### Name

faranak behnaz

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2274 1174

###### Email address

faranak.behnaz@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-07-23, 1397/05/01

##### Expected recruitment end date

2019-07-23, 1398/05/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluating the Effect of Dexmedetomidine Infusion on Gene Expression of Inflammatory Cytokines & Lymphocyte T CD4 + Transcription Factors in Elective Abdominal Aortic Aneurysm Repair

##### Public title

Evaluating the Effect of Dexmedetomidine Infusion on Gene Expression of Inflammatory Cytokines & Lymphocyte T CD4 + Transcription Factors in Elective

Abdominal Aortic Aneurysm Repair

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients with abdominal aortic aneurysms referring to Shohadaye Tajrish Hospital who are candidates for elective aneurysm repair surgery will be included in the study.

### Exclusion criteria:

Previous history of aortic surgery ASA Class III and above IBD Malignancies Chronic inflammatory diseases Taking corticosteroids Emergency surgery Any unstable patient during surgery Any addiction

## Age

No age limit

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Investigator
- Outcome assessor

## Sample size

Target sample size: **30**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Based on random numbers, the patient and the individual who fill the table are unaware

## Blinding (investigator's opinion)

Double blinded

## Blinding description

The patient and anesthetist who fill the table are unaware of the study

## Placebo

Not used

## Assignment

Parallel

## Other design features

-

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

##### Street address

Vel'yanjak Ave Shahid Beheshti University

##### City

Tehran

##### Province

Tehran

##### Postal code

1989934148

##### Approval date

2018-09-04, 1397/06/13

##### Ethics committee reference number

IR.SBMU.RETECH.REC.1397.348

## Health conditions studied

### 1

#### Description of health condition studied

Abdominal Aortic Aneurysm

#### ICD-10 code

-

#### ICD-10 code description

-

## Primary outcomes

### 1

#### Description

Relative level of mRNA; IL6

#### Timepoint

Before the beginning of the intervention (beginning of the study), the first day and the third day, and the time of discharge

#### Method of measurement

Sampling from patient's blood and filling in the questionnaire

### 2

#### Description

Relative level of mRNA; TNF- $\alpha$

#### Timepoint

Before the beginning of the intervention (beginning of the study), the first day and the third day, and the time of discharge

#### Method of measurement

Sampling from patient's blood and filling in the questionnaire

### 3

#### Description

Relative level of Foxp3 mRNA

#### Timepoint

Before the beginning of the intervention (beginning of the study), the first day and the third day, and the time of discharge

#### Method of measurement

Sampling from patient's blood and filling in the questionnaire

### 4

#### Description

Relative level of GATA3mRNA

#### Timepoint

Before the beginning of the intervention (beginning of the study), the first day and the third day, and the time of discharge

**Method of measurement**

Sampling from patient's blood and filling in the questionnaire

**5**

**Description**

Relative level of IL-1mRNA

**Timepoint**

Before the beginning of the intervention (beginning of the study), the first day and the third day, and the time of discharge

**Method of measurement**

Sampling from patient's blood and filling in the questionnaire

**6**

**Description**

Relative level of ROR-

**Timepoint**

Before the beginning of the intervention (beginning of the study), the first day and the third day, and the time of discharge

**Method of measurement**

Sampling from patient's blood and filling in the questionnaire

**7**

**Description**

Relative level of T-bet mRNA

**Timepoint**

Before the beginning of the intervention (beginning of the study), the first day and the third day, and the time of discharge

**Method of measurement**

Sampling from patient's blood and filling in the questionnaire

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

The intervention group was subjected to anxiolytic infusion with doses of 0.3 mg / kg / hour doses of DEX until aortic clamp. Patients' blood samples were taken to determine the level of inflammatory cytokines and the level of expression of inflammatory mRNAs in the preoperative period, after induction of anesthesia, 24 hours after surgery, 4 days after surgery, and at discharge time, from a patient's peripheral blood sample size And the effect of DEX on them will be investigated.

**Category**

Diagnosis

**2**

**Description**

Control group: There are no interventions in this group.

**Category**

Diagnosis

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Shohada Tajrish Hospital

**Full name of responsible person**

faranak behnaz

**Street address**

Tajrish Square Hospital Shohada Tajrish

**City**

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h.ariannia@yahoo.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

nahid asadi

**Street address**

Velenjak Av; Yemen Street

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tehran

**Province**

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**Phone**

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**Email**

nahidasasadi25@yahoo.com

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Shahid Beheshti University of Medical Sciences

**Proportion provided by this source**

25

**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**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
faranak behnaz  
**Position**  
assistant professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Anesthesiology  
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## Person responsible for scientific inquiries

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assistant professor  
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**Other areas of specialty/work**  
Anesthesiology  
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## Person responsible for updating data

**Contact**  
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**Full name of responsible person**  
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**Postal code**  
1989934148  
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nahidasadi25@yahoo.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**  
Yes - There is 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**  
A portion of the information, such as information on the main outcome or the like, can be shared  
**When the data will become available and for how long**  
1399  
**To whom data/document is available**  
Researchers working in academia and academia  
**Under which criteria data/document could be used**  
Analyzes on the delivered data are allowed  
**From where data/document is obtainable**  
Shohada Tajrish Hospital Department of Anesthesiology - Maidan Tajrish Building No. 1 Second Floor Operation Room Dr. Behnaz Telephone 22741174 Shohada Tajrish Hospital - Tajrish Square Building No. 1 Second Floor Ms. Arinnia Telephone 22718002 Internal 310  
**What processes are involved for a request to access data/document**  
Apply for one month  
**Comments**

