

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- α 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- α

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

Tehran

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Tehran

Postal code

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+98 21 2274 1174

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Email

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

City

tehran

Province

Tehran

Postal code

1989934148

Phone

+98 21 2243 2572

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

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
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Position
assistant professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

Contact
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nahid asadi
Position
Consultant
Latest degree
Master
Other areas of specialty/work
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1989934148
Phone
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Email
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

