

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

A comparative study of the function of the kidney after Endovascular Aneurysm Repair (EVAR) and open surgery in patients with the infra renal abdominal aortic aneurysm

Protocol summary

Study aim

Comparison of renal function after Endovascular Aneurysm Repair (EVAR) and open surgery in patients with the infrarenal Abdominal Aortic Aneurysm

Design

Clinical trial, comparative study with two arm parallel group, without blindness postoperative outcome assessment

Settings and conduct

Comparison of renal function in patients with the infra renal abdominal aortic aneurysm treated with Endovascular Aneurysm Repair (EVAR) and open surgery using RIFLE criteria and GFR done in 4 steps after surgery

Participants/Inclusion and exclusion criteria

Patients with the infra renal abdominal aortic aneurysm

Intervention groups

1_EVAR 2_Open surgery

Main outcome variables

prevention of renal function loss after abdominal aortic aneurysm repair; improving the quality of life after surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190617043916N1**
Registration date: **2019-06-23, 1398/04/02**
Registration timing: **retrospective**

Last update: **2019-06-23, 1398/04/02**

Update count: **0**

Registration date

2019-06-23, 1398/04/02

Registrant information

Name

Elham Zaebi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3427 1680

Email address

elham.zaebi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-06-21, 1395/04/01

Expected recruitment end date

2019-06-22, 1398/04/01

Actual recruitment start date

2016-03-20, 1395/01/01

Actual recruitment end date

2019-06-22, 1398/04/01

Trial completion date

2019-06-22, 1398/04/01

Scientific title

A comparative study of the function of the kidney after Endovascular Aneurysm Repair (EVAR) and open surgery in patients with the infra renal abdominal aortic aneurysm

Public title

Renal dysfunction after EVAR and open surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Have the infrarenal Aneurysm of Aort

Exclusion criteria:

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample sizeTarget sample size: **133**Actual sample size reached: **50****Randomization (investigator's opinion)**

N/A

Randomization description**Blinding (investigator's opinion)**

Not 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 Kermanshah University of
Medical Sciences**Street address**

Attar Blvd, moallem town, Kermanshah

City

Kermanshah

Province

Kermanshah

Postal code

6714893486

Approval date

2019-06-12, 1398/03/22

Ethics committee reference number

IR.KUMS.REC.1398.236

Health conditions studied**1****Description of health condition studied**

Infra renal abdominal aortic aneurysm

ICD-10 code

I71.4

ICD-10 code description

Abdominal aortic aneurysm, without mention of rupture

Primary outcomes**1****Description**Renal dysfunction after EVAR and open surgery in
patients with the infrarenal Abdominal Aortic Aneurysm
using RIFLE criteria**Timepoint**Calculate the filtration rate immediately after operation.A
month later, Six months later, and a year later**Method of measurement**

RIFLE CRITERIA

Secondary outcomes

empty

Intervention groups**1****Description**Intervention group: 1_EVAR, patients with the infra renal
abdominal aortic aneurysm treated with Endovascular
Aneurysm Repair. Intervention group: open surgery,
patients with the infra renal abdominal aortic aneurysm
treated with open endoaneurysmoraphy surgery**Category**

Treatment - Surgery

Recruitment centers**1****Recruitment center****Name of recruitment center**

ImamReza hospital

Full name of responsible person

Ali sorush

Street address

Zakariya Razi Blvd, Kermanshah

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lrhk@kums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Farid Najafi

Street address

Shahid Beheshti Blvd

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Kermanshah

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6715847141

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+98 83 3835 8258

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Daftarriasat@kums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Kermanshah 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**

Kermanshah University of Medical Sciences

Full name of responsible person

Elham Zaebi

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific**inquiries****Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

MohamadReaza Sobhiyeh

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

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Person responsible for updating data**Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Elham Zaebi

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

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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

All information is published after non - detection of individuals.

When the data will become available and for how long

After published

To whom data/document is available

Every one

Under which criteria data/document could be used

For trial study

From where data/document is obtainable

MohamadReaza sobhiyeh, Mreza.Sobhiyeh@yahoo.com

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

Using email, one moth after read

Comments