

Endovascular repair after aortic dissection type I or conservative – aortic remodeling enhancement (ERADICARE) trial

Submission date 08/02/2022	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 15/02/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 14/02/2022	Condition category Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

An aortic dissection is a serious condition in which a tear occurs in the inner layer of the body's main artery (aorta) and requires urgent surgery to prevent death.

The aim of this study is the investigation of the long term outcomes of the surgical technique of Transcatheter Endovascular Aortic Repair (TEVAR).

Who can participate?

Adult patients who were submitted to surgery for aortic dissection De Bakey type I restoration 1 to 6 months before re-examination.

What does the study involve?

Patients are followed up after surgery at 1, 6, and 12 months

What are the possible benefits and risks of participating?

None

Where is the study run from?

Evangelismos General Hospital (Greece)

When is the study starting and how long is it expected to run for?

February 2021 to September 2023

Who is funding the study?

National and Kapodistrian University of Athens (Greece)

Who is the main contact?

Nikolaos Schizas, nikschi@schizas@gmail.com

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

96/31-3-2021

Study information

Scientific Title

Comparative study of aortic remodeling after Transcatheter Endovascular Aortic Repair (TEVAR) versus no intervention in patients previously submitted to surgery due to Aortic dissection type I.

Acronym

ERADICARE

Study objectives

The basic hypothesis of this study is that the implementation of TEVAR in patients that were previously submitted to surgery for acute aortic dissection type I improves significantly the aortic remodeling. Additionally, we estimate that the complications related to residual dissection of the aorta might be reduced. More specifically, we believe that in the intervention group the false lumen will be reduced in a greater degree in benefit of the true lumen of the aorta compared to the control group

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 31/03/2021, Bioethics Board of Evangelismos General Hospital (Ypsilantou 45-47, Athens, Greece, 10676; +30 2132041000; sseh@evaggelismos-hosp.gr), ref: 96/31-3-202

Study design

Interventional randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Prevention

Participant information sheet

See additional files (in Greek)

Health condition(s) or problem(s) studied

Investigation of aortic remodeling after Transcatheter Endovascular Aortic Repair (TEVAR) in patients who were previously submitted to surgery for restoration of type I aortic dissection.

Interventions

This is a comparative prospective study which is performed in "Evangelismos" General Hospital of Athens. All patients who are submitted to surgery for aortic type I dissection and are eligible for participation according to the inclusion criteria are randomized through an electronic program into two groups.

The control group is constituted from all the patients in whom no further intervention was performed after the initial surgery and the intervention group, in which the patients who were submitted to TEVAR, are included.

Patients of both groups are re-examined in 1-6 and 12 months through CT angiography.

Intervention Type

Procedure/Surgery

Primary outcome measure

Measured using the RadiAnt app at baseline, 1, 6, 12 months

1. Aortic diameter.
2. Diameter of true lumen.
3. Diameter of false lumen.
4. False lumen thrombosis.

Secondary outcome measures

Measured using patient's medical record, the hospital's database at the fixed re-examination dates or when the patient's clinical status requires.

1. Survival.
2. Need for endovascular repair in the control group (crossover)

3. Days of hospitalization.
4. The impact of anticoagulation or antiplatelet therapy in aortic remodeling.
5. Major complications including:
6. Lethal rupture.
7. Disguised aortic rupture.
8. Clinical manifestations due to aortic dissection progress as splachnic ischemia, renal dysfunction, malperfusion of legs.
9. Manifestations related to TEVAR (etc obstruction of arterial branch)
10. Renal insufficiency related to contrast administration.
11. Stroke.
12. Infections related or not related to the intervention.
13. Neurological complications as paraparesis.
14. Vascular complications related to TEVAR (etc femoral artery injury or ischemia of the leg due to peripheral vessel obstruction).
15. Any clinical manifestation that requires re-admission to hospital.

Overall study start date

01/02/2021

Completion date

01/09/2023

Eligibility

Key inclusion criteria

1. Patients who were submitted to surgery for aortic dissection De Bakey type I restoration 1 to 6 months before re-examination.
2. Entry point presence in descending thoracic aorta.
3. Greatest diameter of aorta more than 40mm.
4. Greatest diameter of false diameter more than 20mm.
5. Patient's informed consent.
6. Informed consent for TEVAR.

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

The total target number of participants is 30, 15 in each group. This number was defined after Power Analysis of the study.

Key exclusion criteria

1. Findings of severe complicated aortic dissection including neurological complications, renal insufficiency or any severe complication that increases morbidity or mortality. The clinical status is estimated in the first re-examination after discharge.

2. Previous open or endovascular interventions of aorta, major branches or peripheral vessels.
3. Technically not feasible TEVAR.
4. Death within less than 30 days.
5. Intraoperative restoration of aortic arch and descending thoracic aorta (Frozen Elephant Trunk).

Date of first enrolment

01/03/2022

Date of final enrolment

01/03/2023

Locations

Countries of recruitment

Greece

Study participating centre

Evangelismos General Hospital

Ypsilantou 45-47

Athens

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Sponsor information

Organisation

Evangelismos General Hospital

Sponsor details

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Sponsor type

Hospital/treatment centre

Website

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Funder(s)

Funder type

University/education

Funder Name

National and Kapodistrian University of Athens

Alternative Name(s)

University of Athens

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

Greece

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

01/01/2024

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from nickschizas@gmail.com

IPD sharing plan summary

Available on request

Study outputs

Output type

[Participant information sheet](#)

Details

Date created

Date added

14/02/2022

Peer reviewed?

No

Patient-facing?

Yes