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

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered			
08/02/2022		☐ Protocol			
<b>Registration date</b> 15/02/2022	Overall study status Completed	Statistical analysis plan			
		Results			
<b>Last Edited</b> 14/02/2022	Condition category Surgery	Individual participant data			
		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, nikschizas@gmail.com

# Contact information

#### Type(s)

Scientific

#### Contact name

Mr Nikolaos Schizas

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# Additional identifiers

#### Clinical Trials Information System (CTIS)

Nil known

#### ClinicalTrials.gov (NCT)

Nil known

#### Protocol serial number

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 artic 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

## Study type(s)

Prevention

# 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(s)

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.

## Key secondary outcome(s))

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 a ortic 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.

#### Completion date

01/09/2023

# **Eligibility**

#### Key inclusion criteria

- 1. Patients who were submitted to surgery for a ortic 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** 

#### Healthy volunteers allowed

No

## Age group

Adult

#### Sex

All

### 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 Greece 10676

# Sponsor information

#### Organisation

**Evangelismos General Hospital** 

# 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**

# Individual participant data (IPD) sharing plan

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

# **IPD sharing plan summary** Available on request

# Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			14/02/2022	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes