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

Submission date 08/02/2022	**Recruitment status** No longer recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 15/02/2022	**Overall study status** Completed	
Last Edited 14/02/2022	**Condition category** Surgery	

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

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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 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.

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

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