Minimal Invasive Extracorporeal Circulation versus conventional cardiopulmonary bypass in patients undergoing cardiac surgery (MiECS)

A Randomized Controlled Trial

Conventional CPB

is not as safe and effective as MiECC

In real-word conventional CPB

is absolutely safe and effective in cardiac surgery

Evidence-based guidelines

2019 EACTS/EACTA/EBCP guidelines on cardiopulmonary bypass in adult cardiac surgery		
MiECC should be considered over standard conventional CPB systems to increase the biocompatibility of ECC.	**IIA**	**B**
MiECC should be considered over standard conventional CPB systems to reduce blood loss and the need for transfusion.	**IIA**	**B**
A combination of MiECC features - such as coating, the centrifugal pump, the separation of cardiotomy suction blood and the use of closed systems - should be considered to improve conventional CPB.	**IIA**	**C**
2021 STS/SCA/AmSECT/SABM update to the clinical practice guidelines on patient blood management		
Minimally invasive extracorporeal circulation is reasonable to reduce blood loss and red cell transfusion as part of a combined blood conservation approach.	**IIA**	**B**
2017 EACTS/EACTA guidelines on patient blood management for adult cardiac surgery		
MiECC systems should be considered over standard conventional CPB systems to reduce perioperative transfusions.	**IIA**	**B**

Question

“Is MiECC a better perfusion technique compared to conventional CPB in cardiac surgery in terms of reducing the incidence of serious perfusion-related clinical complications ? “

Aims and objectives

AIM:

- Test the hypothesis that MiECC is **effective** compared to cCPB for most cardiac surgery operations using ECC

Objectives:

I. Estimate difference (cCPB-MIECC) in the **% of participants having the primary, composite outcome** at **30 days** post-op.

II. Estimate differences (cCPB-MIECC) in **secondary outcomes**

Research question: "Outcomes"

PRIMARY:

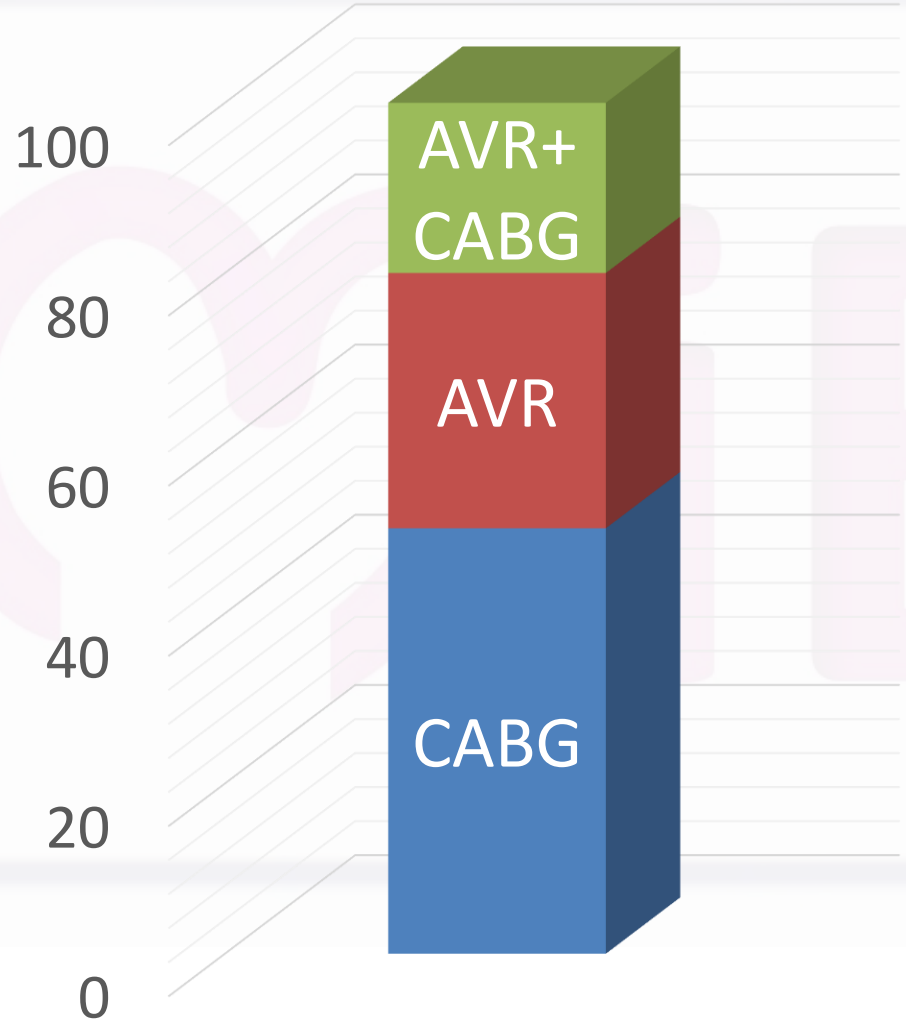
- Composite of 12 post-op serious adverse events, at 30 days after surgery:

• Death	• Mechanical ventilation > 48 hrs, including multiple episodes
• Type 5 MI (4th Universal definition)	• Re-intubation
• Stroke (CT or MRI), with new focal/generalised deficit)	• Re-operation
• Acute kidney injury (AKIN criteria)	• Septicemia confirmed by microbiology

SECONDARY:

- Blood products transfused; postoperative AF; cardiac ICU & hospital stay; other serious adverse events; HRQoL (EQ-5D)

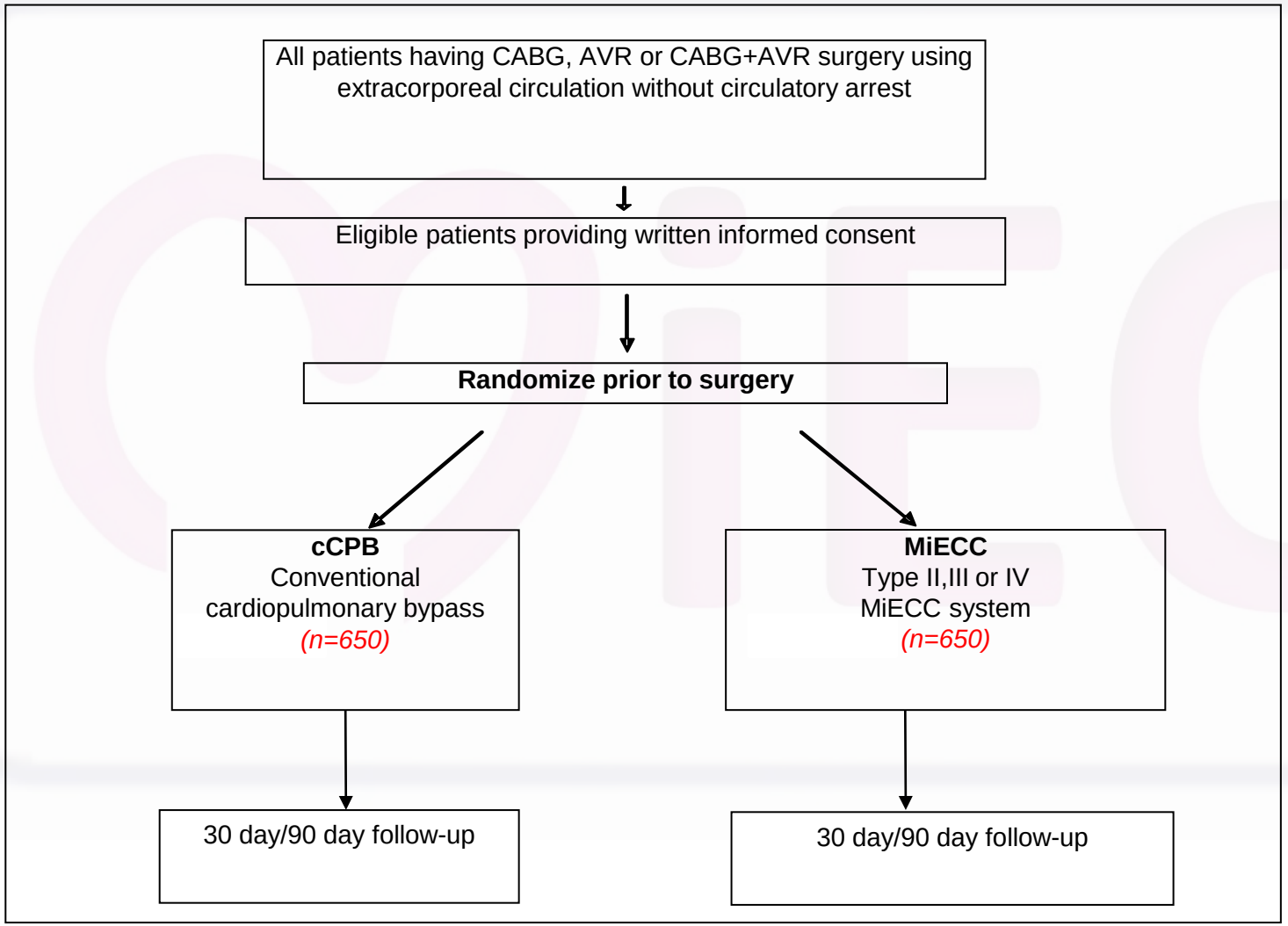
Procedures



Eligibility criteria

- A participant may enter the trial if ALL of the following apply:
  - Age ≥18 and <85 years
  - Undergoing any elective or urgent CABG, AVR surgery, or CABG+AVR surgery, using extracorporeal circulation without circulatory arrest.
- A patient may not enter trial if ANY of the following apply
  - Requirement for emergency or salvage operation
  - Requirement for major aortic surgery (e.g. aortic root replacement)
  - Contraindication or objection (e.g. Jehovah's Witnesses) to transfusion of blood products.
  - Congenital or acquired platelet, red cell or clotting disorders (patients with iron deficient anaemia will not be excluded)
  - Inability to give informed consent for the trial (e.g. learning or language difficulties).

Trial schema



Target sample size:

- 1,300

Target difference:

- Risk ratio ≈ 0.70
- Outcome % CECC ≈ 20%
- Risk difference ≈ 6%

Study centres

Thessaloniki (Greece)	Ankara (Turkey)	Bern (Switzerland)	Hull (UK)
Papworth (UK)	Braunschweig (Germany)	Ulm (Germany)	Bari (Italy)
Toronto (Canada)	Hammersmith (UK)	Göttingen (Germany)	Coswig (Germany)
Kiel (Germany)	Regensburg (Germany)	Ancona (Italy)	Berlin (Germany)

Minimally invasive extracorporeal circulation versus conventional cardiopulmonary bypass in patients undergoing cardiac surgery (MiECS): a randomised controlled trial

Details of Coordinating Centre

Clinical Research Unit (CRU)
Special Unit for Biomedical Research and Education (SUBRE)
Aristotle University of Thessaloniki (AUTh), School of Medicine
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Special Unit for Biomedical Research and Education

An initiative of School of Medicine of Aristotle University of Thessaloniki in promoting biomedical research and education based on interdisciplinary approaches that include medicine, biology, genetics, molecular biology, pharmacology and bioinformatics

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What we do

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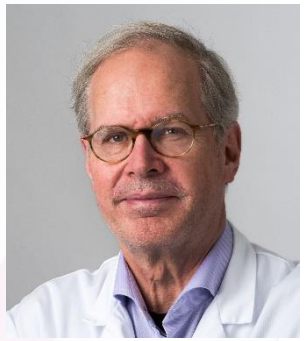
- The UK Heart Valve Registry
- The UK Cardiac Surgery Registry
- Hong Kong national cardiac surgery registry
- And over 300 local clinical databases in hospitals in Europe and 40+ countries (e.g. Denmark, Belgium, Switzerland, Ireland, UK etc)



Trial Steering Committee and Data Monitoring and Safety Committee

Trial Steering Committee (TSC)

- **Chair:** John Murkin, Professor of Anesthesiology (Senate), Department of Anesthesiology and Perioperative Medicine, Schulich School of Medicine & Dentistry, London, Ontario, Canada.
- Thierry Carrel, Professor of Cardiac Surgery, Department of Cardiac Surgery, University Hospital of Zurich, Switzerland
- Vasilios Vasilikos, Professor of Cardiology, School of Medicine AUTh, Greece.
- Mark Bennett, Consultant Anesthesiologist, Swansea Bay University Health Board, UK.
- Georgios Karapanagiotidis, Ass. Professor of Cardiothoracic Surgery, School of Medicine AUTh, Greece.

In addition, key members of the research team and the Coordinating Centre will be invited to attend as non-voting members:

Trial representatives

- Kyriakos Anastasiadis, Professor of Cardiac Surgery, School of Medicine AUTh, Greece.
- Andreas Liebold, Professor of Cardiac Surgery, Department of Cardiac Surgery, University of Ulm. Germany.
- Prakash Punjabi, Professor, Consultant Cardiac Surgeon, Department of Cardiothoracic Surgery, Hammersmith Hospital, Imperial College Healthcare NHS Trust, United Kingdom.
- Polychronis Antonitsis, Assoc. Professor of Cardiothoracic Surgery, School of Medicine AUTh, Greece

Coordinating Centre representative

- Georgios Papazisis, Assoc. Professor of Clinical Pharmacology, School of Medicine AUTh, Greece.

Data Monitoring and Safety Committee (DMSC)

- **Chair:** Panagiotis Bamidis, Professor of Medical Physics, Informatics and Medical Education, School of Medicine AUTh, Greece.
- Asterios Karagiannis, Professor Emeritus, Aristotle University of Thessaloniki, Executive Director, Special Unit for Biomedical Research and Education.
- Theodoros Karamitsos, Assoc. Professor of Cardiology, School of Medicine AUTh, Greece.
- Anna-Bettina Haidich, Statistician, Assoc. Professor, School of Medicine AUTh, Greece.

Key members of the trial team will attend open sessions of DMSC meetings to provide report on progress and provide any additional information requested.