ARIA STUDY

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Sponsored by
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A randomised controlled trial to assess the clinical, technical and cost-effectiveness of a cloud-based, **AR**tificially **I**ntelligent image fusion system in comparison to standard treatment to guide endovascular **A**ortic aneurysm repair **(ARIA)**

Trial design

Phase III multi-centre, open-label, two-armed, randomised controlled clinical trial

n=340

randomised

1:1

- **170 intervention**
- **170 control**

Primary objective

To assess the effect of Cydar EV Maps on procedure time in comparison to standard treatment in endovascular aortic aneurysm repair

Secondary objectives

1. **Procedural efficiency as assessed by:**
   - Anaesthetic duration
   - X-ray dose per procedure
   - Contrast dose per procedure
   - Consumable use per procedure
2. **Technical effectiveness, as assessed by:**
   Proximal and distal seal zone at least 10mm and no evidence of endoleak
3. **Patient outcomes, as assessed by:**
   - Length of HDU admission
   - Length of ITU admission
   - Post-operative total length of hospital stay
   - 30-day mortality
   - Re-intervention
   - Adverse events
   - Quality of life
4. **Cost effectiveness, as assessed by:**
   - Total resource use and costs
   - Quality-adjusted life years (QALYs)
   - Incremental cost per QALY

Inclusion criteria

1. Clinical diagnosis of AAA or TAAA suitable for endovascular treatment, as determined by CT imaging and multi-disciplinary review by the treating team
2. Fit for endovascular repair as determined by the operating team
3. CT imaging must be in accordance with 'Cydar EV Maps: Instructions for Use'
4. Written informed consent
5. Age 18 years and above at the time of consent

Exclusion criteria

Patients unable to provide written informed consent

Abbreviations

AAA: Abdominal aortic aneurysm
CT: Computerised tomography
HDU: High-dependency unit
ITU: Intensive therapy unit
QALY: Quality-adjusted life year
TAAA: Thoracoabdominal aortic aneurysm

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Cydar Medical

CE 2797 FDA CLEARED HIPAA & GDPR Compliant ISO 27001 & ISO 13485 Certification

Cydar EV is a class IIB medical device under EU regulation MDR 2017/745