

The UK-COMPLex Aneurysm Study

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UK – leader in aortic research

- UK- SAT
- UK- EVAR I and II
- MASS
- IMPROVE
- ETTAA

- What is the best treatment for complex aortic aneurysms ?
 - Juxtarenal
 - Pararenal
 - Short neck

A Risk-adjusted and Anatomically Stratified Cohort Comparison Study of Open Surgery, Endovascular Techniques and Medical Management for Juxtarenal Aortic Aneurysms



Team

- **Mr. Colin Bicknell**, Imperial College Healthcare NHS Trust
- **Mr. Jonathan Boyle**, Cambridge University Hospitals NHS Trust
- **Professor John Brennan**, Royal Liverpool University Hospitals NHS Trust
- **Mr Paul Hayes**, Cambridge University Hospitals NHS Trust
- **Professor Ian Loftus**, St George's healthcare NHS Trust
- **Mr Vince Smyth**, Central Manchester University Hospitals NHS Foundation Trust

- **Dr Jai Patel**, Leeds Teaching Hospitals NHS Trust
- **Dr Peter Rowlands**, Royal Liverpool University Hospitals NHS Trust

- **Professor William (Bruce) Campbell**, Royal Devon & Exeter NHS Foundation Trust
- **Dr Andrew Cook**, University of Southampton

- **Dr Alan Haycox**, University of Liverpool

- **Miss Charlotte Rawcliffe**, Liverpool cancer Trials Unit

- **Dr Richard Jackson**, University of Liverpool

- **Ms Clare Perkins**, Public Health England
- **Mr Sacha Wyke**, Public Health England



Objective 1: To compare different treatment strategies corrected for confounding characteristics

Objective 2: To identify if a particular characteristic gives better outcomes with a particular treatment strategy.

Objective 3: To compare different treatment in terms of overall survival and long-term treatment failure

Objective 4: To perform cost effectiveness analyses in terms of quality adjusted life years

Objective 5: To establish the clinical and cost utility of FEVAR and of off-label standard EVAR, in patients who are considered physiologically unfit for OSR, and to compare these against medical management.

Inclusion criteria:

- Elective Juxtarenal AAA repair in England
 - juxtarenal defined into 4 strata of anatomical complexity – Corelab
- Juxtarenal AAA \leq 55 mm and placed on Medical Management 'Operation-deferred'.

Exclusion criteria:

- Aneurysm neck anatomy suitable for standard infrarenal EVAR within IFU of any CE marked device
- Emergency operations
- Surgeon-modified devices
- Thoracic or thoracoabdominal aneurysms
- 'Medical Management Operation Declined' patients

Primary endpoints:

- **Early:** Death
- **Late follow-up:** Mortality, aneurysm-related mortality

Secondary endpoints:

- **Early:** Paraplegia, secondary intervention, organ system complications, stent-graft complications
- **Late follow-up:** Secondary intervention, stent-graft complications (device-related renal failure requiring dialysis, target vessel loss, endoleak types 1, 2, 3, endoleak of undetermined type, endotension, device kinking, limb occlusion, device structural disintegration, distal embolisation,) graft infection, graft rupture incisional hernia – untreated / operated, anastomotic aneurysm, anastomotic-enteric fistula, renal infarction. Potential effects of smoking, alcohol and depression on outcome measures.
- **PROMs:**
- **Quality of Life measures:**
 - EuroQuol EQ-5D 5SL
 - Aneurysm-DQoL
 - Aneurysm-SRQ
 - Aneurysm TSQ
- **Resource use diary**

Public and patient Involvement (PPI)

Programme Management Group (PMG)

Study Steering Committee (SSC)

Data Monitoring and Ethics Committee (DMEC)

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