



Immediate Management of the Patient with Rupture: Open Versus Endovascular repair

Protocol Summary

Patient & centre eligibility:

- The trial will include **ALL** patients with an in-hospital clinical diagnosis of ruptured AAA. This will include patients transferred from other hospitals with a diagnostic CT scan.
- Fluid restriction protocol for all eligible patients
- Centre volume eligibility criteria will be applied

Patient exclusions (will be documented):

- Patients with known connective tissue disorders (e.g. Marfan syndrome).
- Patient with known previous repair of an abdominal aortic aneurysm.
- Deeply unconscious or moribund patients.

Consent & information (pre- and post-operative):

Assess patient's ability to consent:

- Where patient **is** able to consent, read the consent form to the patient
- Where patient is **not** able to consent, refer to a relative or carer if available
- Where patient is **not** able to consent and **no relative or carer** is available, alternative routes to randomisation e.g. Mental Capacity Act in England and Wales may be used
- Discuss participation with patient, relative, carer or other legal representative
- When the patient is awake and fully aware following the operation, discuss with them the trial, providing them with "Post-operative Patient Information" sheet and discuss continuing participation

Randomisation (usually by local telephone number):

- For consented patients, telephone randomisation takes <2 minutes.
- Randomisation will be stratified by centre.

Procedure:

- Determined by randomisation, half of the patients require immediate CT scan to determine suitability for EVAR. CT scans assessed in a core laboratory

Follow up (active for 12 months):

- Following operation, notify patient's family/general practitioner
- Patients discharged following AAA repair will be required to attend an outpatients appointment at 3 and 12 months where follow up information will be obtained:
 - EuroQol form completed (3 & 12 months)
 - "Health Resources" questionnaire for the patient (3 & 12 months)
 - CT scan for patients with endovascular repair (3 months only)
- Re-interventions and hospital admissions recorded to 12 months
- Deaths to 5 years