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# Angioplasty and stent for renal artery lesions

**Submission date**
02/05/2001

**Recruitment status**
No longer recruiting

**Registration date**
02/05/2001

**Overall study status**
Completed

**Last Edited**
15/08/2024

**Condition category**
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**Protocol serial number**
G0000995

## Study information

**Scientific Title**
Angioplasty and stent for renal artery lesions

**Acronym**

ASTRAL

## Study objectives
The ASTRAL trial is designed to address the issue of whether renal arterial revascularisation with balloon angioplasty and/or endovascular stenting can safely prevent progressive renal failure among a wide range of patients with atherosclerotic renovascular disease.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Not provided at time of registration

## Study design
Randomised controlled trial

## Primary study design
Interventional

## Study type(s)
Not Specified

## Health condition(s) or problem(s) studied
Nephrology

## Interventions
Patients in both arms will receive active intervention:
1. In the revascularisation arm, balloon angioplasty and/or endovascular stenting with medical management
2. In the medical therapy arm, drugs will be prescribed as considered appropriate

## Intervention Type
Other

## Phase
Not Specified

## Primary outcome(s)
The primary outcome measure is decline in renal function, as assessed by the slope of the reciprocal creatinine plot against time. Although single measures of serum creatine are a poor indicator of renal function in individual patients, serial measurements over up to 5 years will be made so patterns of change will be detectable. Furthermore, the assessment of differences in renal function between the two treatment arms with reciprocal creatine plots is statistically appropriate since the important factor is the average change in renal function with or without revascularisation.

## Key secondary outcome(s))
Secondary end points are: blood pressure, urinary protein excretion; serious vascular events (such as myocardial infarction or stroke) and other event rates (including death and the need for dialysis); safety; and a single measure of angiographic patency at one year (in a subset of patients).

### Completion date
01/10/2007

## Eligibility

### Key inclusion criteria
1. Atherosclerotic renovascular disease (ARVD) confirmed angiographically
2. At least one ARVD lesion that is suitable for revascularisation
3. No definite indication for, or contraindication to, revascularisation, and revascularisation unlikely to become definitely indicated within 6 months of entry
4. Informed consent obtained from patient

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Not Specified

### Sex
Not Specified

### Key exclusion criteria
1. Non-atherosclerotic renal arterial lesion (i.e. fibromuscular dysplasia).
2. Previous revascularisation procedure for ARVD.
3. Clear contraindication to revascularisation.

Eligibility will be based on the "uncertainty principle". That is, if there is a clear indication for, or contraindication to, revascularisation, that patient is not eligible for entry into ASTRAL. If, on the other hand, the patient's medical team is uncertain whether or not to revascularise, then that patient is eligible for randomisation. This approach allows an appropriately heterogeneous population of patients to be entered (since different clinicians will have varying areas of uncertainty), thereby leading to results which are more generalisable to the 'real world' and permitting investigation of treatment effects in different types of patient.

### Date of first enrolment
01/09/2000

### Date of final enrolment
01/10/2007

## Locations

### Countries of recruitment
United Kingdom

England

**Study participating centre**
**University of Birmingham Clinical Trials Unit**
Birmingham
United Kingdom
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# Sponsor information

**Organisation**
University of Birmingham (UK)

**ROR**
https://ror.org/03angcq70

# Funder(s)

**Funder type**
Research council

**Funder Name**
Medical Research Council (MRC) (UK)

**Alternative Name(s)**
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

**Location**
United Kingdom

# Results and Publications

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 12/11/2009 | | Yes | No |
| Results article | Long Term Outcomes | 15/08/2024 | 15/08/2024 | Yes | No |
| Interim results article | interim results | 01/07/2007 | | Yes | No |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |