

Angioplasty and stent for renal artery lesions

Submission date 02/05/2001	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 02/05/2001	Overall study status Completed	☐ Protocol
Last Edited 15/08/2024	Condition category Urological and Genital Diseases	☐ Statistical analysis plan
		☒ 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

Primary study design

Interventional

Study design

Randomised controlled trial

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
B15 2RR

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, Medical Research Committee and Advisory 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