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Angioplasty and stent for renal artery lesions

Submission date	Recruitment status	[_] Prospectively registered
02/05/2001	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
02/05/2001	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
15/08/2024	Urological and Genital Diseases	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.astral.bham.ac.uk/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

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 measure
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.

Secondary outcome measures
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).

Overall study start date
01/09/2000

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
750

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
England

United Kingdom

Study participating centre
University of Birmingham Clinical Trials Unit
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Sponsor information

Organisation
University of Birmingham (UK)

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Sponsor type
University/education

Website

http://www.bham.ac.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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Interim results article	interim results	01/07/2007		Yes	No
Results article	results	12/11/2009		Yes	No
Results article	Long Term Outcomes	15/08/2024	15/08/2024	Yes	No