

To investigate the effect of methylprednisolone on inflammatory cytokines and urinary N-Beta-D-glucosaminidase /creatinine ratio in elective aortic aneurysm repair

Submission date 08/03/2007	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 30/04/2007	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 24/03/2011	Condition category Circulatory System	☐ 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
AN05/6839

Study information

Scientific Title

Study objectives

That methylprednisolone given before ischaemia and subsequent reperfusion may attenuate renal damage in patients undergoing elective open aortic aneurysm repair

Ethics approval required

Old ethics approval format

Ethics approval(s)

Leeds West Local ethics committee, approved on 4 April 2005. Ref: 05/Q1205/31

Primary study design

Interventional

Study design

Double blind randomised controlled trial

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Abdominal aortic aneurysm

Interventions

10 mg/kg methylprednisolone or dextrose placebo in equal volume given before ischaemia and subsequent reperfusion

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

methylprednisolone

Primary outcome(s)

Urinary N-acetyl-beta-D-glucosaminidase (Beta-NAG) levels over the first post operative week (at baseline, 1 hour, 2, 6, 24 and 48 hours post cross clamp release).

Key secondary outcome(s)

Urinary albumin and alpha-1 microglobulin levels over the first post operative week (at baseline, 1 hour, 2, 6, 24 and 48 hours post cross clamp release).

Completion date

01/06/2006

Eligibility

Key inclusion criteria

Patients presenting to the Vascular Unit for elective abdominal aortic aneurysm repair will be invited to take part. Patients will be aged between 18 and 75.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

Key exclusion criteria

Patients will be free to withdraw from the study at any time without having to give any reason and without prejudice to clinical care.

1. Diabetic patients
2. Active proven infection
3. Already on steroids
4. Systemic fungal infection
5. Acute renal failure
6. On renal replacement therapy
7. Pregnant or lactating

Date of first enrolment

01/06/2005

Date of final enrolment

01/06/2006

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Academic Unit of Anaesthesia

Leeds

United Kingdom
LS1 3EX

Sponsor information

Organisation

Leeds General Infirmary (UK)

ROR

<https://ror.org/04hrjej96>

Funder(s)

Funder type

Research organisation

Funder Name

The Association of Anaesthetists of Great Britain and Ireland (UK)

Funder Name

Anaesthetic Research Society (UK)

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	01/01/2008		Yes	No