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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
08/03/2007		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
30/04/2007	Completed	[X] 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

Contact name

Dr Simon Turner

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Study design

Double blind randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Prevention

Participant information sheet

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 measure

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).

Secondary outcome measures

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).

Overall study start date

01/06/2005

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

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

Target number of participants

20

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

Date of final enrolment 01/06/2006

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Academic Unit of Anaesthesia
Leeds
United Kingdom
LS1 3EX

Sponsor information

Organisation

Leeds General Infirmary (UK)

Sponsor details

c/o Dr Johanathan Gower 6th Floor Wellcome Wing Leeds General Infirmary Leeds England United Kingdom LS1 3EX

Sponsor type

Hospital/treatment centre

Website

http://www.leedsteachinghospitals.com/patients/aboutus/hospitals/lgi.php

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

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?
Results article	results	01/01/2008		Yes	No