ISRCTN21626059 https://doi.org/10.1186/ISRCTN21626059

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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/04/2007	**Overall study status** Completed	
Last Edited 24/03/2011	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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

01/06/2005

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