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A randomised trial comparing two strategies for preventing kidney failure after angioplasty

Submission date	Recruitment status	[_] Prospectively registered
07/05/2009	Stopped	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
15/07/2009	Stopped	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
06/08/2014	Urological and Genital Diseases	[_] Record updated in last year

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
805

Study information

Scientific Title
A randomised factorial trial of N-acetylcysteine prophylaxis and iso-osmolar versus low-osmolar contrast media on kidney function in patients at risk of contrast-induced nephropathy following cardiac catheterisation for percutaneous coronary interventions

Acronym
CONNECT

Study objectives
1. We hypothesise that N-acetylcysteine antioxidant prophylaxis prevents deterioration of renal impairment and may improve survival
2. We also hypothesise that use of iso-osmolar contrast media prevents deterioration of renal function in patients at high risk of contrast-induced nephropathy (CIN)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Submitted via Integrated Research Application System (IRAS) approval pending as of 07/05/2009

Primary study design
Interventional

Study design
Randomised controlled open-label trial with 2 x 2 factorial design

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Kidney function impairment/coronary artery disease/contrast-induced nephropathy

Interventions
All patients undergoing cardiac catheterisation with the intention of percutaneous coronary intervention (definite PCI or catheterisation +/- PCI) that meet the inclusion criteria will be randomised to receive prophylactic N-acetylcysteine or not, with or without iso- and low-osmolar contrast media.

Study arms:
Arm 1: iso-osmolar contrast media
Arm 2: iso-osmolar contrast media + N-acetylcysteine
Arm 3: low-osmolar contrast media
Arm 4: low-osmolar contrast media + N-acetylcysteine

N-acetylcysteine will be given with a loading dose of 1,200 mg orally prior to the procedure on the day followed by 1,200 mg bulk oral dose for a total of four times (up to 48 hours) after the procedure.

Updated 06/08/2014: this trial was stopped before recruitment began in 2011 due to changing practices and procedures, lack of funding and resources and time availability.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
N-acetylcysteine

Primary outcome(s)
eGFR at 6 months

Key secondary outcome(s)
1. Contrast-induced nephropathy. Total duration of follow-up: 6 months.
2. eGFR at 14 days
3. Major Adverse Cardiovascular Events (MACE) death, myocardial infarction (MI), stroke, and repeat revascularisation. Total duration of follow-up: 6 months.
4. Renal replacement therapy. Total duration of follow-up: 6 months.

Completion date
30/06/2011

Reason abandoned (if study stopped)
Lack of funding/sponsorship

Eligibility

Key inclusion criteria
1. Male and female patients aged 18 years or over
2. Estimated glomerular filtration rate (eGFR) less than 60 ml/m (as calculated by modified Modification of Diet in Renal Disease [MDRD] equation with local laboratory correction factor)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Patients who had coronary angiography or other procedure with contrast exposure (computed tomography pulmonary angiography [CTPA] etc.) within 2 weeks of percutaneous coronary intervention (PCI)
2. Unable to consent
3. Patient undergoing cardiac surgery
4. Cardiogenic shock
5. Unlikely to attend for follow-up blood tests

6. Presence of non-cardiac illness that might affect life expectancy
7. Any previous allergic reaction to contrast media or N-acetylcysteine (NAC)

Date of first enrolment
01/07/2009

Date of final enrolment
30/06/2011

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Liverpool Heart and Chest Hospital NHS Trust
Liverpool
United Kingdom
L14 3PE

Sponsor information

Organisation
Liverpool Heart and Chest Hospital NHS Trust (UK)

ROR
https://ror.org/01je02926

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Liverpool Heart and Chest Hospital (UK) - Internal Charitable Trust

Funder Name
Covidien UK Ltd (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration