

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

Submission date 07/05/2009	Recruitment status Stopped	☐ Prospectively registered
		☐ Protocol
Registration date 15/07/2009	Overall study status Stopped	☐ Statistical analysis plan
		☐ Results
Last Edited 06/08/2014	Condition category Urological and Genital Diseases	☐ Individual participant data
		☐ 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

Study design

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

Primary study design

Interventional

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