

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

<b>Submission date</b> 07/05/2009	<b>Recruitment status</b> Stopped	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 15/07/2009	<b>Overall study status</b> Stopped	<input type="checkbox"/> Protocol
<b>Last Edited</b> 06/08/2014	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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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