

The effect of N-acetylcysteine (NAC) on renal functions of patients undergoing cardiac catheterisation

Submission date 12/09/2003	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered
Registration date 12/09/2003	Overall study status Stopped	<input type="checkbox"/> Protocol
Last Edited 27/09/2011	Condition category 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0176115665

Study information

Scientific Title

Study objectives

Contrast material administration in cardiac catheterisation (angiogram/angioplasty) is associated with a deterioration in kidney function of some patients with underlying renal impairment. Recent studies suggest that NAC may reduce such complication but it is not clear whether this effect is sustained for long periods or clinically relevant. We therefore would like to propose a study to find out the medium term effect of NAC on the kidney functions of these patients and their clinical relevances. In addition, we would also like to investigate whether there is any significant change in blood markers of inflammation such as vascular cell adhesion molecule-1 (VCAM-1) and isoprostanes with the use of NAC in this group of patients. This may help to explain the mechanism of contrast material induced kidney injury and protective effect of NAC.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Urological and Genital Diseases: Renal function

Interventions

Not provided at time of registration.

Added June 2008: trial abandoned.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

N-acetylcysteine (NAC)

Primary outcome measure

1. Change in serum creatinine (short and medium term)
2. VCAM-1 and isoprostanes
3. Length of hospital stay
4. Need for dialysis

Secondary outcome measures

Not provided at time of registration

Overall study start date

15/07/2002

Completion date

31/05/2004

Reason abandoned (if study stopped)

Poor recruitment

Eligibility**Key inclusion criteria**

Not provided at time of registration

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

28 patients, 28 controls, total 56

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

15/07/2002

Date of final enrolment

31/05/2004

Locations

Countries of recruitment

England

United Kingdom

Study participating centre**Department of Cardiology**

Oxford

United Kingdom

OX3 9DU

Sponsor information

Organisation

Department of Health (UK)

Sponsor details

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

Sponsor type

Government

Website

<http://www.doh.gov.uk>

Funder(s)

Funder type

Government

Funder Name

Oxford Radcliffe Hospitals NHS Trust (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