

Fourth Contrast Study: contrast study for patients undergoing diagnostic coronary angiography

Submission date 12/09/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 15/04/2016	Condition category Surgery	<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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0227115061

Study information

Scientific Title

Fourth Contrast Study: contrast study for patients undergoing diagnostic coronary angiography

Study objectives

To compare two contrast agents routinely used in the Cath Lab.

To assess the clinical outcomes and adverse effects of these two agents.

To assess the potential advantage of one over the other.

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)

Hospital

Study type(s)

Diagnostic

Participant information sheet

Health condition(s) or problem(s) studied

Angiography

Interventions

Randomised study of two commonly used contrast agents (NIOPAM and Xenetix). Reactions due to contrast reaction will be recorded in a data collection form which will form the basis for a computer database. Will abide by The Data Protection Act.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

NIOPAM®, Xenetix®

Primary outcome measure

Clinical outcome and adverse effects of the contrast agents.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/08/2002

Completion date

30/09/2003

Eligibility

Key inclusion criteria

1. Patients admitted for cardiac catheterisation.
2. Approximately 2000 subjects.
3. No selection bias to gender or age group.

Participant type(s)

Patient

Age group

Other

Sex

Both

Target number of participants

2000

Key exclusion criteria

Pregnant patients will be excluded, unless patient has life threatening condition.

Date of first enrolment

01/08/2002

Date of final enrolment

30/09/2003

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

The James Cook University Hospital
Middlesbrough
United Kingdom
TS4 3BW

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

Hospital/treatment centre

Funder Name

South Tees 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