

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

Submission date 12/09/2003	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 12/09/2003	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 15/04/2016	Condition category Surgery	☐ Individual participant data
		☐ 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

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Diagnostic

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(s)

Clinical outcome and adverse effects of the contrast agents.

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Other

Sex

All

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**

United Kingdom

England

Study participating centre

The James Cook University Hospital

Middlesbrough

United Kingdom

TS4 3BW

Sponsor information**Organisation**

Department of Health (UK)

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

South Tees Hospitals NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration