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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

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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

Study design
Randomised controlled trial

Primary study design
Interventional

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