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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 [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 15/04/2016	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr YKS Viswanath

Contact details
The James Cook University Hospital
Marton Road
Middlesbrough
United Kingdom
TS4 3BW
+44 (0)1642 854863
yks.viswanath@stees.nhs.uk

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