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Prospective randomised trial comparing computed tomography (CT) and barium enema for colonic investigation in elderly patients

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 30/09/2016	**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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0515103409

Study information

Scientific Title
Prospective randomised trial comparing computed tomography (CT) and barium enema for colonic investigation in elderly patients

Study objectives
Colonic investigation in the elderly is often difficult. Colonoscopy, because of sedation, is associated with increased cardiorespiratory complications in older people. Barium enema is widely utilised but approximately 30% of studies are incomplete in the elderly due to technical difficulties with bowel preparation and incontinence. Additionally, bowel preparation may cause faecal incontinence, sleep disturbance and perianal soreness, and has been associated with altered plasma biochemistry. CT scanning has been investigated as a more acceptable alternative in elderly patients. No bowel preparation is necessary, the scan is quick, and no sedation is required. Although CT is unable to detect colonic polyps without full bowel cleansing, these lesions are unimportant in an elderly symptomatic group. Where colorectal carcinoma is the target lesion, previous studies have compared CT followed by barium enema in elderly symptomatic patients and found CT equally able to detect colorectal carcinoma whilst being technically easier to perform and more acceptable to patients. Furthermore, extracolonic pathology is also visible. There are no prospective, randomised trials of this approach, which is the aim of this study.

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
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Surgery: Colonoscopy

Interventions
It is proposed that all hospital clinician referrals for barium enemas in patients over 75 years of age will be randomised to either CT or barium enema. Those randomised to barium enema will be booked in the usual fashion and the enema performed on a routine oupatient list. These patients will be informed of their inclusion in the trial by letter and consent obtained. Those patients not consenting will be sent a barium enema appointment as requested but their data will not be included in the trial. Those patients randomised to CT will be contacted by letter and invited to have a CT scan instead of a barium enema. Consenting patients will undergo a standard CT of the abdomen and pelvis with oral, and rectal and iv contrast as per usual practice. The CT will be reported in the usual fashion with specific comment as to the normality or otherwise of the colon. Results will be available to the referring clinician as per usual practice who is then free to request any further investigation deemed necessary. All patients will undergo long term follow up with reference made to clinical notes, results of further investigations, surgical notes pathology and post mortem reports and cancer registry data. The efficacy of CT (and barium enema) for detection of colorectal carcinoma will be assessed along with the influence on patient diagnosis and management of any extracolonic pathology detected. Patient experiences of the two tests will be investigated by questionnaire.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
CT assessment of colorectal carcinoma will be made as per published criteria. Patient outcome will be assessed by long term clinical follow up and the use of the results of further radiological and pathological investigations.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/06/2001

Completion date
30/04/2003

Eligibility

Key inclusion criteria
Adults aged 75 years or older

Participant type(s)
Patient

Age group

Senior

Sex
Both

Target number of participants
600

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
01/06/2001

Date of final enrolment
30/04/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
North West London Hospitals NHS Trust
Harrow, Middlesex
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HA1 3UJ

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
North West London 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