

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

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		<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 30/09/2016	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

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Additional identifiers

Protocol serial number
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

Study type(s)

Diagnostic

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 outpatient 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(s)

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.

Key secondary outcome(s)

Not provided at time of registration

Completion date

30/04/2003

Eligibility

Key inclusion criteria

Adults aged 75 years or older

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Senior

Sex

All

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

United Kingdom

England

Study participating centre

North West London Hospitals NHS Trust

Harrow, Middlesex

United Kingdom

HA1 3UJ

Sponsor information

Organisation

Department of Health (UK)

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

North West London Hospitals NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration