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Comparison of the cleansing efficacy of two different bowel preparations for colonoscopy

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 16/12/2014	**Condition category** Surgery	

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
N0065117310

Study information

Scientific Title
Comparison of the cleansing efficacy of two different bowel preparations for colonoscopy

Study objectives
To identify the best or the most effective of the two bowel preparation regimes for successful completion of colonoscopy (Picolax, compared to Picolax and Senna).

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
Surgery: Colonoscopy

Interventions
Operator-blinded prospective study with the use of questionnaires comparing the colonoscopy failure rate due to poor bowel preparation associated with the two different laxative regimes (Picolax and Placebo, compared to Picolax and Senna).

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
icolax and Senna

Primary outcome measure
Completion colonoscopy rates (by reaching the caecum)

Secondary outcome measures
Not provided at time of registration

Overall study start date
30/12/2002

Completion date
01/12/2003

Eligibility

Key inclusion criteria
A total of 374 patients aged above 18 and below 80 are to be recruited.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
187 patients in each treatment group, 374 in total

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
30/12/2002

Date of final enrolment
01/12/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Sunderland Royal Hospital
Sunderland

United Kingdom
SR4 7TP

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
City Hospitals Sunderland 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