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STOOL - Stepped Treatment of Older adults On Laxatives

Submission date	Recruitment status	[_] Prospectively registered
25/04/2003	Stopped	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/04/2003	Stopped	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
25/08/2009	Digestive System	[_] 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
HTA 98/32/99

Study information

Scientific Title

Acronym
STOOL

Study objectives
1. To investigate the clinical and cost effectiveness of bulk forming, stimulant and osmotic laxatives prescribed by primary care to ambulant older people living at home.
2. To investigate the clinical and cost effectiveness of prescribing an additional second type of laxative agent in the treatment of patients whose constipation is not resolved by a single agent.
3. To describe the adherence by patients to treatment protocols.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration.

Study design
Pragmatic factorial randomised trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Constipation

Interventions
Different forms of stepped pharmacological treatment of constipation with economic evaluation. An add-on qualitative study of the meaning and experience of constipation to older people and the views of general practitioners.

Added as of 25/08/2009: the trial was closed after recruiting 19 participants due to problem with recruitment.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
The primary clinical outcome is the reported number of bowel movements per week at the end of each step (6 and 10 weeks after randomisation) and at six months follow-up.

Key secondary outcome(s))
Secondary clinical outcomes include the presence/absence of the other Rome criteria for constipation; adverse effects of treatment (although some of these may also be symptoms of constipation); and relapse rates. In addition to the measurement of these clinical outcomes, patient satisfaction and the impact of the treatment on costs and quality of life will be assessed

Completion date
30/04/2006

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
People aged 55 or over with chronic constipation living in private households.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Key exclusion criteria
Not provided at time of registration.

Date of first enrolment
01/10/2002

Date of final enrolment
30/04/2006

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Centre for Health Services Research
Newcastle upon Tyne
United Kingdom
NE2 4AA

Sponsor information

Organisation
Department of Health (UK)

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2008		Yes	No