

STOOL - Stepped Treatment of Older adults On Laxatives

Submission date 25/04/2003	Recruitment status Stopped	☐ Prospectively registered ☐ Protocol
Registration date 25/04/2003	Overall study status Stopped	☐ Statistical analysis plan ☒ Results
Last Edited 25/08/2009	Condition category Digestive System	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof John Bond

Contact details
Centre for Health Services Research
University of Newcastle upon Tyne
21 Claremont Place
Newcastle upon Tyne
United Kingdom
NE2 4AA
+44 (0)191 222 6777
john.bond@newcastle.ac.uk

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.

Primary study design

Interventional

Study design

Pragmatic factorial randomised trial

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