

Treatment of bowel dysfunction in stroke patients: a randomised controlled trial

Submission date 01/03/2001	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 01/03/2001	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 25/11/2010	Condition category Digestive System	☐ Individual participant data

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
AP0763

Study information

Scientific Title

Study objectives

To evaluate treatment of constipation and faecal incontinence in stroke survivors

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)

Treatment

Health condition(s) or problem(s) studied

Bowel dysfunction

Interventions

Stroke patients within 2 years of their initial acute cerebrovascular accident (CVA) will be screened by a 9-item bowel symptom questionnaire and cognitive assessment. Eligible patients will be randomised to intervention or control groups:

1. The intervention group will undergo a single clinical assessment including a symptom history, rectal examination, and where relevant, an abdominal radiograph leading to a treatment programme consisting of appropriate bowel medications, sphincter exercises where relevant and education with the use of a self-care booklet on all issues relevant to bowel problems in stroke
2. The control group will receive usual care from their hospital or General Practitioner

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Percentage of bowel movements (BMs) per week graded as "normal" by participants in a prospective 1-week stool diary.

Key secondary outcome(s)

1. Percentage of BM graded as normal by the patient and number of faecal incontinence (FI) episodes, measured by postal prospective 7-day stool diary at 1, 3, 6, and 12 months
2. Bowel-related symptoms
3. Visual analogue scores for severity rating
4. Quality of life (bowel-related and 12-item Short Form Health Survey [SF-12])
5. Self-reported treatment
6. Resource use

Completion date

01/01/2004

Eligibility

Key inclusion criteria

1. Symptoms of faecal incontinence, constipation, and/or rectal outlet delay
2. Within 2 years of acute stroke

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex**Key exclusion criteria**

Reporting acute diarrhoea or colonic disease other than diverticular disease

Date of first enrolment

01/01/2003

Date of final enrolment

01/01/2004

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Elderly Care Unit

London

United Kingdom

SE1 7EH

Sponsor information

Organisation

Action Medical Research (UK)

ROR

<https://ror.org/01wcqa315>

Funder(s)

Funder type

Charity

Funder Name

Action Medical Research (UK)

Alternative Name(s)

action medical research for children, actionmedres, The National Fund for Research into Crippling Diseases, AMR

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2004		Yes	No