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

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

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
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
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

Overall study start date
01/01/2003

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
146

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

England

United Kingdom

Study participating centre
Elderly Care Unit
London
United Kingdom
SE1 7EH

Sponsor information

Organisation
Action Medical Research (UK)

Sponsor details
Vincent House
Horsham West Sussex
United Kingdom
RH12 2DP

Sponsor type
Charity

Website
http://www.action.org.uk/

ROR
https://ror.org/01wcqa315

Funder(s)

Funder type
Charity

Funder Name
Action Medical Research (UK)

Alternative Name(s)
actionmedres, action medical research for children, AMR

Funding Body Type

Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

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

Study outputs

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