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

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

## Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

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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

#### Kev 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