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Very Early Rehabilitation or Intensive Telemetry After Stroke (VERITAS)

Submission date 27/08/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/09/2008	**Overall study status** Completed	
Last Edited 27/09/2017	**Condition category** Circulatory 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
05/MRE00/90

Study information

Scientific Title
Very Early Rehabilitation or Intensive Telemetry After Stroke (VERITAS): a pilot randomised controlled trial

Acronym
VERITAS

Study objectives
Very early rehabilitation or intensive monitoring will reduce complications and improve patient recovery after stroke.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee Scotland (A) MREC. Date of approval: 22/12/2005 (ref: 05/MRE00/90)

Study design
Single-blind, factorial (2 x 2) pilot randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Acute stroke

Interventions
The participants were randomly allocated to the following four arms:

1. Standard care: Early transfer to an established multidisciplinary stroke unit where they will receive conventional stroke unit care within an established stroke service

2. Early mobilisation plus standard care: The early mobilisation interventions are based on the AVERT trial (see below), and will begin within 24 hours of the onset of the symptoms. The protocol is functional and task specific and can be summarised as follows:
a. Mobilisation should commence as soon as possible on the stroke unit
b. Bedrest should be avoided if at all possible
c. Patients will be encouraged to be up, sitting and transferring at least 4 times per day

d. Any vulnerable hemioplegic shoulder will be cared for using supports when sitting, transferring and walking

The primary objective is to increase the frequency of mobilisation. The protocol will be delivered by the research nurse, under the supervision of a trained physiotherapist. During the first 3 days after stroke the stroke patients will be observed closely for abnormalities of heart rate, oxygen saturation and blood pressure during mobilisation. If there are any abnormalities during these procedures, mobilisation will be discontinued. The five stages for monitoring are as follows:
i. Before mobilisation (lying in bed)
ii. Sitting upright in bed
iii. Sitting on the edge of the bed
iv. After five minutes sitting on the edge of the bed
v. After transferring to a chair

The duration of each early mobilisation intervention will be determined by the patient tolerance but will range between 5 and 30 minutes per session. The research nurse trained in the intervention will be available on the ward during weekdays as will be supervising physiotherapist. The intervention will continue for at least 7 days or until discharge whichever is sooner.

3. Automated physiological monitoring: Standard care plus a protocol based on the Gateshead trial (see below) guiding the continuous monitoring. This will use an established commercial system (Welch Allyn Inc), which will include the possibility of ambulatory monitoring. The protocol will include advice on responding to abnormalities of heart rate or rhythm, blood pressure, temperature, oxygen level or blood glucose. Routine monitoring will be continued for the first three days and extended beyond then if persisting abnormalities are identified. After this time patients will revert to standard care. The research nurse will devote time to ensuring the monitoring protocol is followed.

4. A combined protocol incorporating both 2 and 3 above

Total duration of interventions: 1 week
Total duration of follow-up: 3 months

Information on the AVERT trial can be found at http://www.ncbi.nlm.nih.gov/pubmed/18706042

Information on the Gateshead trial can be found in the 1998 British Geriatrics Society autumn meeting abstract (http://www.ncbi.nlm.nih.gov/pubmed/10450456) - Davis M, Hollyman C, McGiven M, Chambers I, Egbuji J, Barer D. Physiological monitoring in acute stroke. Age Ageing 1999 (Suppl):P33

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The following will be monitored for 7 days:
1. Feasibility (especially treatment contamination)
2. Acceptability of the trial process
3. Safety of the trial process: early complications and adverse events

Note: The primary outcome of the proposed main trial will be the proportion of patients dead or disabled (Modified Rankins Score 3-5) at 3 months post stroke.

Secondary outcome measures
Patient activity, recorded for 7 days using automated activity monitors which record the time spent lying, sitting, standing or walking.

Overall study start date
01/03/2007

Completion date
01/02/2008

Eligibility

Key inclusion criteria
Individuals (both males and females) admitted to hospital with symptoms of new stroke within 24 hours of symptom onset (with the primary objective of recruiting individuals within 12 hours of symptom onset).

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
20

Key exclusion criteria
1. Individuals with severe pre-stroke disability
2. Those who have made a full recovery
3. Severe comorbidities which would prevent their participation in the trial

Date of first enrolment
01/03/2007

Date of final enrolment
01/02/2008

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Academic Section of Geriatric Medicine
Glasgow
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G31 2ER

Sponsor information

Organisation
Greater Glasgow and Clyde NHS Board (UK)

Sponsor details
East Research Office
Glasgow Royal Infirmary
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84 Castle Street
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Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/05kdz4d87

Funder(s)

Funder type
Charity

Funder Name
Chest, Heart and Stroke Scotland (Ref: 05/A87)

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 of pilot study	01/09/2010		Yes	No