

Very Early Rehabilitation or Intensive Telemetry After Stroke (VERITAS)

Submission date 27/08/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 30/09/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 27/09/2017	Condition category Circulatory System	<input type="checkbox"/> 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
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

Study type(s)

Treatment

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 hemiplegic 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(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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**

United Kingdom

Scotland

Study participating centre

Academic Section of Geriatric Medicine

Glasgow

United Kingdom

G31 2ER

Sponsor information**Organisation**

Greater Glasgow and Clyde NHS Board (UK)

ROR

<https://ror.org/05kdz4d87>

Funder(s)

Funder type

Charity

Funder Name

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

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 of pilot study	01/09/2010		Yes	No