

# Very Early Rehabilitation or Intensive Telemetry After Stroke (VERITAS)

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

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 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 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  
United Kingdom  
G31 2ER

## **Sponsor information**

**Organisation**  
Greater Glasgow and Clyde NHS Board (UK)

**Sponsor details**  
East Research Office  
Glasgow Royal Infirmary  
4th Floor Walton Building  
84 Castle Street  
Glasgow  
Scotland  
United Kingdom  
G4 0SF

**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?
<a href="#">Results article</a>	results of pilot study	01/09/2010		Yes	No