ISRCTN98129255 https://doi.org/10.1186/ISRCTN98129255

A Very Early Rehabilitation Trial (AVERT)

Submission date	Recruitment status	[_] Prospectively registered
19/02/2014	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/03/2014	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
05/10/2016	Circulatory System	

Plain English summary of protocol

Background and study aims
Since 1991, many clinical researchers have believed that an early start to rehabilitation helps people with stroke recover to a greater extent than those who don't get early rehabilitation. Although some hospitals in Scandinavia have adopted the practice, research by our group has shown that early rehabilitation practices (and physical activity levels of people with stroke) vary considerably between countries. Uncertainty about the safety and effectiveness of the practice of early rehabilitation has hindered development in this field. Our group have been studying early rehabilitation since 2001. We have developed and tested a study in a small group of people with stroke and shown that it is feasible and safe to start rehabilitation within 24 hours of the first signs of stroke. This research tests whether starting active rehabilitation early is better than usual rehabilitation practices in hospitals. Specifically we will test early rehabilitation comprising out-of-bed activities (with the help of nurses and physiotherapists) starting within 24 hours of the onset of stroke and continuing frequently throughout the first two weeks after stroke. We are testing whether this can reduce the number of people who die from their stroke or suffer ongoing disability. We are also interested in whether the treatment helps to reduce the number of medical complications (such as chest infections, falls, bed sores) experienced by people who have suffered a stroke and whether it improves the quality of life of people in the long term (at 12 months). Finally, the study sets out to test whether this form of treatment is cost-effective compared to current care.

Who can participate?
Patients admitted to a stroke unit with a recent stroke (within 24 hours).

What does the study involve?
Participants are randomly allocated to either a treatment group or a control group. Those who are assigned to the control group have usual care in the stroke unit. Those assigned to the treatment group are assisted to get out of bed within 24 hours of the first sign of stroke by a trained nurse and/or physiotherapist. This early out of bed activity continues frequently, throughout the day, 6 days a week for the first 14 days after stroke or until discharge out of the stroke unit (whichever comes first). They also receive usual stroke care. All participants are followed up at home or wherever they are residing first at 3 months and again 9 months later. At these times, a trained health care worker will spend about an hour with the participant and his

or her carer gathering information about their ability to move about, carry out normal activities, their mood, thoughts about their quality of life, and any costs that have been associated with their stroke care.

What are the benefits and risks of participating?
All participants will receive the best available care in their hospital stroke unit. There is some evidence that rehabilitation helps people recover after a stroke. It is therefore possible that your participation in this project will help your recovery. We cannot promise the study will help you but the information we get from this study will help us to further understand how we can better treat patients with stroke in the future. We do not expect any side effects from the treatments offered. However, it is possible that some people may find active mobilisation tiring. One of the aims of the research is to monitor any side-effects that may occur in each of the groups. We have completed an initial study that indicates that this form of early rehabilitation is not harmful. However, in this very early time after stroke serious health issues (complications) commonly arise and it is important that any possible risks that may be attributable to the treatment are carefully monitored. We have an external committee (Data Safety and Monitoring Committee) whose role is to keep a close eye on all serious health issues that arise throughout the course of the study. They will tell us if they believe that the treatment is harmful and should be modified or stopped.

Where is the study run from?
The study is international and is being coordinated from the Florey Research Institute in Melbourne, Australia. The UK lead clinician is Professor Peter Langhorne at the University of Glasgow. Over 20 hospitals around the UK have local research teams who are managing this study in their hospital.

When is the study starting and how long is it expected to run for?
The study started in Australia in 2006 and in the UK in 2009. The study finished recruitment in October 2014 and is now in the follow-up phase until October 2015.

Who is funding the study?
National Institute of Health Research (NIHR) (UK) , National Health and Medical Research Council (NHMRC) (Australia) , Stroke Association (UK) , Chest Heart and Stroke Scotland (UK) and Chest Heart and Stroke Northern Ireland (UK).

Who is the main contact?
Main contact for the international study is Assistant Professor Julie Bernhardt (j.bernhardt@unimelb.edu.au)
For participants and researchers in the UK the main contact is Professor Peter Langhorne (peter.langhorne@glasgow.ac.uk).

Study website
http://www.florey.edu.au/research/avert

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 12/01/16, ACTRN12606000185561

Study information

Scientific Title
A Very Early Rehabilitation Trial (AVERT): a prospective phase 3, multicentre, randomised controlled trial of efficacy (death and disability at 3 months) and cost-effectiveness of very early rehabilitation (early and more frequent rehabilitation sessions) versus standard care (the rehabilitation care a patient would normally receive) in patients with acute stroke

Acronym
AVERT

Study objectives
Earlier and more intensive rehabilitation with a focus on mobilisation out of bed (termed Very Early Mobilisation; VEM) - when compared with standard stroke unit rehabilitation practices - lead to:
1. Reduced death or disability at 3 months post stroke (primary outcome)
2. Fewer and less severe complications (especially complications of immobility)
3. Better quality of life at 12 months
4. A cost-effective system of care

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/120116
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0006/117429/PRO-12-01-16.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)

1. Scotland A REC, 03/10/2008, ref: 3/10/08
2. North Wales REC, 20/02/2009, ref: 20/2/09

Study design
Phase III single-blind randomised controlled trial with concealed randomisation blinded assessment of outcomes and intention-to-treat analysis

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 to request a patient information sheet

Health condition(s) or problem(s) studied
Stroke

Interventions
Patients are randomised one of two groups:
1. Control group: usual care in the stroke unit
2. Intervention group: very early rehabilitation within 24 hours of the onset of stroke and for up to 14 days. The rehabilitation consists of protocol-specified rehabilitation sessions of short duration, related to the patients' normal activities of daily living. The rehabilitation is implemented by physiotherapists and nurses. Blinded assessments of outcome is performed at 3 and 12 months.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Modified Rankin Score measured at 3 months after randomisation

Secondary outcome measures
1. Barthel Index
2. Irritability Depression and Anxiety Scale
3. Assessment of Quality of Life Instrument
4. Time to walking 50 meters unassisted
5. Montreal Cognitive Assessment (MoCA) (at 3 months only)
6. Rivermead Motor Assessment Scale

7. Important medical events (falls, stroke progression, recurrent stroke, pulmonary embolism, deep vein thrombosis, myocardial infarction, angina, urinary tract infection, pressure sores, pneumonia, depression), from confirmed source documents.

Overall study start date
01/06/2006

Completion date
01/10/2015

Eligibility

Key inclusion criteria
1. First or recurrent stroke diagnosis
2. Haemorrhage or infarct
3. Admitted to a stroke unit within 24 hours of onset of stroke symptoms.
4. Patients must at least react to verbal commands.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
2104

Key exclusion criteria
1. Pre stroke mRS of 3, 4 or 5 (previous significant disability)
2. Deterioration in patients condition in the first hour resulting in admission to ICU, surgery or documented palliative treatment.
3. Concurrent diagnosis of rapidly deteriorating disease.
4. Unstable coronary or other medical condition which is judged by the investigator to pose a hazard to the patient by involvement in the trial.
5. A confirmed or suspected lower limb fracture preventing implementation of the protocol tPA. Patients can be included if the treating physician permits and mobilisation within 24 hours is permitted.
6. Patients cannot be concurrently recruited to drug or other intervention trials.
7. Vital signs not within protocol specified normal limits.

Date of first enrolment
01/06/2006

Date of final enrolment
16/10/2014

Locations

Countries of recruitment
Australia

Malaysia

New Zealand

Scotland

Singapore

United Kingdom

Study participating centre
Glasgow Royal Infirmary
Glasgow
United Kingdom
G31 2ER

Sponsor information

Organisation
NHS Greater Glasgow and Clyde (UK)

Sponsor details
Research & Development Management Office
The Tennent Institute
Western Infirmary
38 Church Street
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United Kingdom
G11 6NT
+44 (0)141 232 9448
Erica.packard@ggc.scot.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.nhsggc.org.uk/content/default.asp?page=home_Research Development

ROR
https://ror.org/05kdz4d87

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
National Health and Medical Research Council (NHMRC) (Australia)

Alternative Name(s)
NHMRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Australia

Funder Name
Stroke Association (UK)

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype

Associations and societies (private and public)

Location
United Kingdom

Funder Name
Chest, Heart and Stroke Association Scotland

Alternative Name(s)
CHSS

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Funder Name
Northern Ireland Chest, Heart and Stroke Association

Alternative Name(s)
NICHS

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Primary outcome results to be presented in April 2015

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	04/07/2015		Yes	No