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The second intensive blood pressure reduction in acute cerebral haemorrhage trial

Submission date 10/07/2008	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 18/07/2008	**Overall study status** Completed	
Last Edited 12/04/2016	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
An intracerebral haemorrhage (ICH) occurs when a blood vessel in the brain bursts and bleeds into the brain. ICH is one of the most serious types of stroke, affecting over a million people worldwide each year. About one third of people with ICH die soon after and most survivors are left with major long-term disability. Despite the size of the disease burden and the cost on healthcare resources, there remains uncertainty about the role of surgery and medical treatments for ICH. There is evidence that lowering blood pressure (BP) reduces stroke risk. Although BP levels are commonly high early after the onset of stroke, particularly in ICH, the effects of BP lowering treatment in the acute phase of stroke remain unknown. As a consequence, there are wide ranging guideline recommendations for managing high BP. The aim of this study is to assess the effects of early intensive BP lowering on patients with ICH and high BP, compared with more conservative BP management.

Who can participate?
Patients with acute ICH (within 6 hours of onset) and high BP (between 150 and 220 mmHg).

What does the study involve?
Patients are randomly allocated to either intensive or conservative management of BP. Treatment starts as soon as possible after allocation (e.g., in the emergency department) and is continued in a monitored facility (i.e., intensive care unit, high dependency unit or stroke unit). For patients allocated to the intensive BP lowering group the treatment goal is to achieve BP of less than 140 mmHg within one hour of starting treatment. The second goal is to maintain the BP at 140 mmHg or less or at least 7 days in hospital, and subsequently on discharge and for 90 days. Patients allocated to the conservative BP lowering group receive BP management that is based on American Heart Association (AHA) guidelines. In this group, treatment is started if BP is over 180 mmHg. For both groups, patients must be on an oral blood pressure lowering drug by day 7 or at discharge from hospital, with a long-term target BP of 140 mmHg, as per the guidelines. Information is collected at the time of allocation and follow-up data is collected on four occasions: after 24 hours and 7 days (or at the time of death or hospital discharge, if this should occur before day 7), and after 28 days and 90 days, with the last two assessments carried out either in-person or over the telephone.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
The George Institute Royal Prince Alfred Hospital (Australia)

When is the study starting and how long is it expected to run for?
September 2008 to December 2012

Who is funding the study?
National Health and Medical Research Council (NHMRC) (Australia)

Who is the main contact?
Prof Craig Anderson

Study website
http://www.interact2.org/

Contact information

Type(s)
Scientific

Contact name
Prof Craig Anderson

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00716079

Secondary identifying numbers
NHMRC-571281, ACTRN12608000362392

Study information

Scientific Title

An international randomised controlled trial to establish the effects of early intensive blood pressure lowering in patients with intracerebral haemorrhage

Acronym
INTERACT2

Study objectives
The purpose of this academic lead study is to determine if a treatment strategy of early intensive blood pressure (BP) lowering compared to conservative BP lowering policy in patients with elevated blood pressure within 6 hours of acute intracerebral haemorrhage (ICH) improves the outcome of death and disability at 3 months after onset.

Ethics approval required
Old ethics approval format

Ethics approval(s)
SSWAHS Ethics Review Committee (RPAH Zone), 26/06/2008, ref: 08/RPAH/273

Study design
Multicentre treatment parallel-assignment two-armed open-label randomised active-controlled safety/efficacy study

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 contact cdelcourt@george.org.au or canderson@george.org.au to request a patient information sheet

Health condition(s) or problem(s) studied
Intracerebral haemorrhage

Interventions
Intensive arm:
Intensive blood pressure (BP) lowering therapy is given via an intravenous drip for 24 hours. The target is to reach a systolic BP less than 140 mmHg within 1 hour.

Conservative arm:
Patients will receive management of BP that is based on a standard guideline, as published by the American Heart Association (AHA). The attending clinician may consider commencing BP treatment if the systolic level is greater than 180 mmHg, however and the first line treatment will be oral (including nasogastric if required) and/or transdermal routes. Should control of

systolic BP not be achieved via these routes, intravenous treatment may be started until the target systolic BP of 180 mmHg is achieved.

Intervention:
Blood pressure management policies:
The trial is an assessment of BP lowering management strategies, using routinely available drugs. There is some flexibility in the use of particular BP lowering agents to achieve BP targets.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Labetalol hydrochloride, metoprolol tartrate, hydralazine hydrochloride, glycerol trinitrate, phentolamine mesylate, nicardipine, urapidil, esmolol, clonidine, enalaprilat, nitroprusside

Primary outcome measure
A composite of death or dependency, with dependency being defined by a score of 3 to 5 on the Modified Rankin Scale (mRS). Timeframe: 90 days.

Secondary outcome measures
1. Death and dependency in patients treated less than 4 hours
2. Death
3. Dependency
4. Health Related Quality of Life (HRQoL)
5. Physical function
6. Recurrent vascular events
7. Days of hospitalisation
8. Permanent residential care

Timeframe: 90 days

Overall study start date
01/09/2008

Completion date
31/12/2012

Eligibility

Key inclusion criteria
1. Patients with computed tomography (CT)-confirmed spontaneous intracerebral haemorrhage (ICH)
2. Elevated systolic blood pressure (greater than 150 mmHg and less than 220 mmHg)
3. Capacity to commence randomly assigned treatment within 6 hours of onset of ICH
4. Able to be 'actively' treated and admitted to a monitored facility
5. Male and female, aged older than 18 years old

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
2839

Key exclusion criteria
1. Clear indication or contraindication to intensive BP lowering
2. Evidence ICH secondary to a structural abnormality
3. Use of thrombolytic agent
4. Previous ischaemic stroke within 30 days
5. A very high likelihood that the patient will die within the next 24 hours on the basis of clinical and/or radiological criteria
6. Score of 3 - 5 on the Glasgow Coma Scale (indicating deep coma)
7. Significant pre-stroke disability or advanced dementia
8. Planned early neurological intervention
9. Participation in another clinical trial
10. A high likelihood that the patient will not adhere to the study treatment and follow-up regimen

Date of first enrolment
01/09/2008

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
Argentina

Australia

Austria

Belgium

Brazil

Chile

China

Finland

France

Germany

Hong Kong

India

Italy

Netherlands

Norway

Pakistan

Portugal

Spain

Switzerland

United Kingdom

United States of America

Study participating centre
The George Institute Royal Prince Alfred Hospital
Sydney
Australia
2050

Sponsor information

Organisation
National Health and Medical Research Council (NHMRC) (Australia)

Sponsor details
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Sponsor type
Research council

Website
http://www.nhmrc.gov.au/

ROR
https://ror.org/011kf5r70

Funder(s)

Funder type
Research council

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

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?

Basic results			No	No
Results article	pilot study results	01/05/2008	Yes	No
Protocol article	protocol	01/04/2010	Yes	No
Results article	results	01/04/2012	Yes	No
Results article	results	20/06/2013	Yes	No
Results article	results	01/04/2014	Yes	No