

The Glucose Insulin in Stroke Trial (GIST)

Submission date 23/01/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 01/09/2022	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

Contact name
Prof Christopher Gray

Contact details
Sunderland Royal Hospital
Department of Medicine for the Elderly
Kayll Road
Sunderland
United Kingdom
SR4 7TP
+44 (0)191 565 6256 ext 41245
chris.gray@chs.northy.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RRCC37R R/1805/7005

Study information

Scientific Title

The Glucose Insulin in Stroke Trial (GIST)

Acronym

GIST UK

Study objectives

Objectives:

To determine by means of a multi-centre randomised controlled clinical trial whether outcome from acute stroke can be favourably influenced by glucose/potassium/insulin induced and maintained euglycaemia.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Multi-centre randomised controlled trial with blinded outcome assessments

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet**Health condition(s) or problem(s) studied**

Cardiovascular diseases: Cerebrovascular disease

Interventions

1. Treatment with intravenous 10% glucose solution, 20 mmol KCL and Actrapid insulin (initial insulin 16 units/500ml) at 100 ml per hour.
2. Control treatment with intravenous N saline at 100 ml per hour. Treatment is continued for 24 hours with the objective in the treatment group to maintain blood glucose between 4-7 mmol/L.

Results:

Target recruitment 2,500 patients to detect a minimum 6% difference in mortality at 5% level, power 80%.

Conclusion:

This is the first ever clinical trial of glucose/potassium/insulin induced and maintained euglycaemia following stroke the results of which will be available in late 2006.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

All-cause mortality at 12 weeks.

Secondary outcome measures

Proportion of patients with a poor outcome (modified Rankin score 4 - 6) at 12 weeks between treatment groups.

Overall study start date

01/09/2002

Completion date

30/06/2006

Eligibility

Key inclusion criteria

All acute stroke patients (less than 24 hours onset) with cerebral infarction (CI) or primary intracerebral haemorrhage (PICH) and admission plasma glucose greater than 6.1 and less than 17 mMol/l.

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

2500

Key exclusion criteria

1. Subarachnoid haemorrhage
2. Renal failure (urea 320 mMol/l or creatinine 3200 mMol/l)
3. Anaemia (Hb less than 9.0 g/dl)
4. Coma
5. Isolated posterior circulation syndromes with no physical disability
6. Pure language disorders
7. Established history of insulin dependent diabetes mellitus
8. Previous disabling stroke (Modified Rankin score 3)
9. Established diagnosis of dementia or abbreviated mental test score less than 7/10
10. Symptomatic cardiac failure - New York Heart Association (NYHA) Grade 3 or 4

Date of first enrolment

01/09/2002

Date of final enrolment

01/02/2006

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Sunderland Royal Hospital

Sunderland

United Kingdom

SR4 7TP

Sponsor information

Organisation

NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details

The Department of Health

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

<http://www.doh.gov.uk>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

NHS Executive Northern and Yorkshire (UK)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications		01/03/2003		Yes	No
Other publications		01/01/2004		Yes	No
Other publications		01/01/2004		Yes	No
Results article		01/05/2007		Yes	No