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The Glucose Insulin in Stroke Trial (GIST)

Submission date 23/01/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/01/2004	**Overall study status** Completed	
Last Edited 01/09/2022	**Condition category** Circulatory System	

Plain English Summary
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
RRCC37R R/1805/7005

Study information

Scientific Title
The Glucose Insulin in Stroke Trial (GIST)

Acronym
GIST UK

Study hypothesis
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

Condition
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

Overall study end date
30/06/2006

Eligibility

Participant 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

Participant 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

Recruitment start date
01/09/2002

Recruitment end date
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