ISRCTN31118803 https://doi.org/10.1186/ISRCTN31118803

# The Glucose Insulin in Stroke Trial (GIST)

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

**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

**Protocol serial number**
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

## Primary study design
Interventional

## Study design
Multi-centre randomised controlled trial with blinded outcome assessments

## Study type(s)
Treatment

## 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(s)
All-cause mortality at 12 weeks.

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

### 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

### Healthy volunteers allowed
No

### Age group
Not Specified

### Sex
Not Specified

### 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
United Kingdom

England

### Study participating centre

**Sunderland Royal Hospital**
Sunderland
United Kingdom
SR4 7TP

# Sponsor information

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

# Funder(s)

### Funder type
Hospital/treatment centre

### Funder Name
NHS Executive Northern and Yorkshire (UK)

# Results and Publications

### 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? |
|---|---|---|---|---|---|
| Results article | | 01/05/2007 | | Yes | No |
| Other publications | | 01/03/2003 | | Yes | No |
| Other publications | | 01/01/2004 | | Yes | No |
| Other publications | | 01/01/2004 | | Yes | No |