GLUCOVAS.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25157

Source
Nationaal Trial Register

Brief title
GLUCOVAS

Health condition

acute ischemic stroke; hyperglycemia; acuut herseninfarct; hyperglycemie.

Sponsors and support

Primary sponsor: AMC
Source(s) of monetary or material Support: Third party grant by Novartis

Intervention

Outcome measures

Primary outcome

1. Glycemic control. (Mean glucose throughout protocol treatment; Percentage of time spent within target range);

2. Hypoglycemia (glucose <3.5 mmol/L): Number of hypoglycemic events per group, Number of serious hypoglycemic events (glucose<2.2 mmol/L), Number of symptomatic confirmed hypoglycemic events.

Secondary outcome

1. Clinical outcome (modified Rankin score) at three months;

2. Incidence of pneumonia;

3. Treatment data.

Study description

Background summary

Hyperglycemia has been associated with poor clincal outcome in patients with acute ischemic stroke. Therefore, glycemic control has the potential to improve clinical outcome. Glycemic control, however, appears to be difficult to establish due to postprandial glucose surges and an increased number of hypoglycemic episodes. With this study we investigate if (i) glycemic control in continuous tube fed patients is superior compared to regularly fed patients and (ii) If vildagliptin as add-on therapy to insulin results in less hypoglycemic episodes compared to placebo.

Study objective

1. TGC with insulin in continuous tube fed patients is superior to TGC with insulin in regularly fed patients;

2. Vildagliptin as add-on therapy to insulin mediated TGC results in less hypoglycemic episodes compared to placebo.

Study design

1. 5 days;

2. 3 months.

Intervention

1. IV insulin;

2. Continuous tube feeding;

3. Vildagliptin.

Contacts

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Eligibility criteria

Inclusion criteria

1. Supra-tentorial stroke with a time of onset within 24h before presentation;

2. An acute neurological deficit measurable with the National Institute of Health Stroke Score (see appendix I, NIHSS score) ¡Ý 4 at presentation;

3. Venous plasma admission glucose > 7.0 mmol/l;

4. Informed consent.

Exclusion criteria

1. Signs of cerebral hemorrhage on computed tomography scan;

2. Previous history of diabetes mellitus treated with insulin;

3. Patients in whom death appears imminent;

4. Renal insufficiency defined as creatinine > 150 mmol/L;

5. Patients under the age of 18;

6. Pregnant patients;

7. Expected transfer to a different hospital within 5 days.

Study design

Design

Study type:	Interventional
Intervention model:	Factorial
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	10-07-2009
Enrollment:	30
Type:	Anticipated

Ethics review

Positive opinion

Date:	22-06-2009

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL1764
NTR-old	NTR1874
Other	METC AMC : 08/382
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A