

Intensive five day intravenous insulin treatment combined with enteral feeding in hyperglycemic ischemic stroke patients: a feasibility study

Published: 10-11-2006

Last updated: 20-05-2024

To optimize a safe five-day intensive intravenous insulin treatment post stroke and to assess glucose profiles in patients with stroke and HG on admission, receiving standard continues enteral tube feeding.

Ethical review	Approved WMO
Status	Pending
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON30354

Source

ToetsingOnline

Brief title

Intensive insulin therapy post stroke

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Central nervous system vascular disorders

Synonym

stroke; hyperglycemia

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: enteral feeding, intensive glycemic control, post stroke hyperglycemia

Outcome measures

Primary outcome

Glucose profiles: area under the curve (AUC) > 6.1 mmol/l and AUC <4.4 mmol/l.

Secondary outcome

- 1) Time needed to perform all actions necessary for intensive insulin treatment.
- 2) Adverse reactions
 - a) Hypoglycemic episodes
 - b) Incidence of aspiration pneumonia
 - c) Infection or skin irritation at the site of tube insertion

Study description

Background summary

Post stroke hyperglycemia (HG) has been reported to negatively influence cerebral infarction size, infarct progression and clinical outcome in several series. In non-stroke, prolonged intensive insulin therapy greatly reduces mortality in diabetic patients with acute myocardial infarction and in both diabetic and non diabetic intensive care patients and patients undergoing coronary artery bypass graft surgery. The use of intensive insulin therapy in acute stroke is currently under investigation. Preliminary results indicated a positive, but not significant effect on neurological function. In this trial however patients are treated for only 24h. Both experimental and in vivo studies have shown that in cerebral ischemia the infarct core is surrounded by a rim of viable tissue at risk of infarction: the penumbra. The penumbra is potentially salvageable but further necrosis is also possible. Recruitment of this viable tissue into the infarct core has been related to HG. The penumbra

can persist until five days post stroke. Lack of a significant improvement with glycemic control for 24h only could therefore be explained by insufficient duration of insulin treatment post stroke. Prolonged glycemic control in patients with stroke however is not easy to accomplish. As reported by others and from experience in a recent study we performed, especially postprandial glucose surges are difficult to control. Continuous enteral feeding with a stable flow of nutritional input rather than unlimited access to food supplies therefore has the potential to greatly facilitate prolonged intensive insulin treatment in this patient group.

Study objective

To optimize a safe five-day intensive intravenous insulin treatment post stroke and to assess glucose profiles in patients with stroke and HG on admission, receiving standard continuous enteral tube feeding.

Study design

This is a single center pilot study. Blinding is not possible due to the nature of the treatment. We will include 7 patients. All patients will receive continuous enteral tube feeding and intravenous insulin aiming at plasma glucose values between 4.4 mmol/l and 6.1 mmol/l for five consecutive days. Glucose values will be monitored by serial venous glucose measurements using a bedside Hemocue analyzer. We will use a modified protocol that proved to be successful in maintaining blood glucose levels safely between 4.4 - 6.1 mmol/L in previous trials

Intervention

- 1) Intravenous insulin
- 2) Glucose control with standardized finger-prick procedure.
- 3) Enteral tube feeding

Study burden and risks

Hypoglycemia

The main side effect of intensive insulin therapy is hypoglycemia. Mild hypoglycemia for a short period does not cause any damage in healthy individuals. Prolonged severe hypoglycemia caused by excessive insulin administration in normal individuals can cause neurological damage leading to convulsions, coma and death. Convulsions and coma can be seen in normal human subjects with plasma glucose levels lower than 1.5 mmol/l.

The first physiological response of the body during hypoglycemia is the inhibition of insulin release followed by an increase in glucagon release and other counterregulatory hormones. Autonomic symptoms such as anxiety, pallor, palpitations, restlessness, perspiration, tachycardia, tremor and warmth,

emerge at plasma glucose levels below 3.2 mmol/l. Neuroglycopenic symptoms such as confusion, drowsiness, fatigue, inability to concentrate, irritability, lack of muscular coordination, lightheadedness, paresthesia, personality change, slurred speech and weakness follow if plasma glucose drops below 2,8 mmol/l. These symptoms and the autonomic symptoms are reversible.

Contacts

Public

Academisch Medisch Centrum

(Raad van bestuur) Meibergdreef 9
1105 AZ Amsterdam
Nederland

Scientific

Academisch Medisch Centrum

(Raad van bestuur) Meibergdreef 9
1105 AZ Amsterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Supratentorial ischemic stroke last 24hrs
glucose > 7.0 mmol/l

Exclusion criteria

cerebral hemorrhage
history with diabetes mellitus
decrease consciousness

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	15-10-2006
Enrollment:	7
Type:	Anticipated

Medical products/devices used

Generic name:	enteral tube feeding
Registration:	Yes - CE intended use

Ethics review

Approved WMO	
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
CCMO	NL14206.067.06