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

Published: 03-09-2007
Last updated: 09-05-2024

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	Not approved
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON31195

Source
ToetsingOnline

Brief title
Intensive glycemic control post stroke

Condition

- Other condition
- Embolism and thrombosis

Synonym
hyperglycemia; high blood glucose

Health condition

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, 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 glucoses 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 continues enteral tube feeding.

Study design

This is a multi centre pilot study. Blinding is not possible due to the nature of the treatment. We will include 15-20 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) Intraveneus insulin
2) 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.

Fingerprick:Periodic fingerpricks to control for glucsose values could be inconvenient. During first 24 hrs patients will be monitored for viatal signs each our as in standard care. Fingerpricks will be intergrated in these moments as much as possible.

Enteral tube feeding.
Patients can experience enteral tube feeding as incomfortable. Diarrhea and local skin infections have been reported.

Contacts

Public
Academisch Medisch Centrum

AMC H2-222
1100 DE Amsterdam
Nederland
Scientific
Academisch Medisch Centrum

AMC H2-222
1100 DE Amsterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1) Supratentorial stroke with a time of onset within 24h before presentation.
2) An acute neurological deficit measurable with the National Institute of Health Stroke Score (NIHSS, see appendix B) > 4 at presentation.
3) Venous plasma admission glucose > 7.0 mmol/l 5) Informed consent.

Exclusion criteria

1) Signs of cerebral hemorrhage on computed tomography scan.
2) Previous history of diabetes mellitus and treatment with insulin.
3) Decreased consciousness (Glasgow Coma Scale < 8).
4) Patients in whom death appears imminent.
5) Patients under the age of 18
6) Pregnant patients
7) Patients admitted from a different coverage area.
8) When another patient is already included at that time.

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	20
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Actrapid
Generic name:	Insulin
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	03-09-2007
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Not approved Date:	23-10-2007
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
EudraCT	EUCTR2007-004464-40-NL
CCMO	NL19371.041.07