Continuous glucose monitoring in acute ischemic stroke:
a prospective study of the feasibility of continuous glucose monitoring and evolution of glucose in acute ischemic stroke patients suitable for endovascular treatment

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We aim to assess the feasibility of continuous glucose monitoring with CGM in patients with acute ischemic stroke who are eligible for endovascular treatment. In addition, we will assess the evolution of glucose levels in these patients.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Central nervous system vascular disorders
Study type	Observational invasive

Summary

ID

NL-OMON52090

Source
ToetsingOnline

Brief title
Continuous glucose monitoring in acute ischemic stroke (GASP-study)

Condition

- Central nervous system vascular disorders

Synonym
Ischemic stroke

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: Ministerie van OC&W,Voor de pilot zullen 20 sensoren worden aangeschaft;dit wordt gefinancierd vanuit de stichting wetenschappelijk onderzoek neurologie Isala

Intervention

Keyword: Endovascular, Glucose, Monitoring, Stroke

Outcome measures

Primary outcome

Feasibility of using CGM in the acute phase will be the main parameter in the pilot study. In this stage we will consider if it is logistically feasible to implant the CGM in this acute setting. In addition, the accuracy of CGM in acute ischemic stroke will be tested.

1. logistical feasibility will be defined as number of patients who complete 24 hours of glucose monitoring. There will be concluded that CGM is feasible when monitoring is successful for 24 hours in 75% of the included patients. Delay in start of of endovascular treatment due to implantation (5 minutes delay is determined as reasonable) and adverse events will be specifically assessed..

2. accuracy of CGM, will be determined by parallel capillary finger prick at 10.00 AM and 12.00; 14.00; 16.00; 18.00 and 20.00 PM. Glucose values will also be determined by venous measurements at 08.00 AM (fasting glucose); 10.00 AM and 15.00 PM. According to previous literature the point accuracy of CGM versus interstitial based glucose values was determined with the Parkes error grid analysis. Values in zones A and B are described as clinically acceptable.

Values in zones C,D and E are determined as inaccurate. CGM is accurate when

95% of the CGM measurements are in zones A and B.

Secondary outcome

Secondary study outcome consist of stroke severity assessed with NIHSS-score

and core and penumbra volume on admission CT-perfusion respectively

Study description

Background summary

Hyperglycemia on admission is common in patients with acute ischemic stroke. Increased glucose levels have been associated with larger infarct volume and worse functional outcome after both intravenous thrombolysis and endovascular treatment. Hence, glucose lowering therapy might be an effective therapeutic target in acute ischemic stroke patients. However, several studies showed no effect of lowering glucose on infarct size or functional outcome. None of these studies focused on recanalization treatment and the majority started with the glucose lowering intervention outside the acute window of ischemic stroke. Also, they failed to realise target glucose levels in the intervention group and capillary plasma glucose monitoring was appeared to be difficult. By using continuous glucose monitoring, glucose levels can be assessed continuously and an intervention can be adjusted to current glucose values.
Our aim is to assess the feasibility of continuous glucose monitoring in acute ischemic stroke with continuous glucose monitoring devices (CGM) in patients who are eligible for endovascular treatment. In addition, we will assess the temporal profile of hyperglycemia in these patients.

Study objective

We aim to assess the feasibility of continuous glucose monitoring with CGM in patients with acute ischemic stroke who are eligible for endovascular treatment. In addition, we will assess the evolution of glucose levels in these patients.

Study design

This study will be an exploratory intervention study and will be conducted in two phases. During a pilot phase, the feasibility of continuously measuring glucose in the acute phase of stroke will be observed. When this is feasible, during phase 2, the evolution of glucose during the first 24 hours after acute

stroke will be assessed. A separate application or an amendment will then be submitted for this.

Study burden and risks

Using the information generated in this study, a future glucose lowering intervention can be more specified for example in terms of the most effective window of the intervention. Also, by using continuously monitoring during a glucose lowering, this intervention can be adapted to current glucose levels. Other possible variables that must be taken into account include pre-existing diabetes, age and the type and degree of recanalization. Because this knowledge, a future glucose lowering intervention could provide smaller infarct volumes and better functional outcome after ischemic stroke.
During comparable studies, except for some moderate skin reactions, no patients adverse events were reported. Safe and accurately use of CGM in the acute setting has also been shown in the context of treatment on the intensive care unit. Hence, significant knowledge can be gained while patients undergo their regular treatment without added risks due to CGM.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Acute ischemic stroke
18 years or over
Intracranial occlusion
Eligible for endovascular treatment

Exclusion criteria

No specific

Study design

Design

Study phase:	2
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-02-2022
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	04-11-2021
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	04-11-2021
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	11-05-2022
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	11-05-2022
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	09-08-2022
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	09-08-2022
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)

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	NL78000.075.21