

GLUCOVAS.

Gepubliceerd: 22-06-2009 Laatste bijgewerkt: 18-08-2022

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.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25157

Bron

Nationaal Trial Register

Verkorte titel

GLUCOVAS

Aandoening

acute ischemic stroke; hyperglycemia; acuut herseninfarct; hyperglycemie.

Ondersteuning

Primaire sponsor: AMC

Overige ondersteuning: Third party grant by Novartis

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

Hyperglycemia has been associated with poor clinical 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.

Doel van het onderzoek

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.

Onderzoeksopzet

1. 5 days;
2. 3 months.

Onderzoeksproduct en/of interventie

1. IV insulin;
2. Continuous tube feeding;
3. Vildagliptin.

Contactpersonen

Publiek

Academic Medical Center
University of Amsterdam
P.O. Box 22700
Nyika Kruyt
Department of Neurology
H2-218
Academic Medical Center
University of Amsterdam
Amsterdam 1100 DE
The Netherlands
+31 20 566 3547

Wetenschappelijk

Academic Medical Center
University of Amsterdam
P.O. Box 22700
Nyika Kruyt
Department of Neurology
H2-218
Academic Medical Center
University of Amsterdam
Amsterdam 1100 DE
The Netherlands
+31 20 566 3547

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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) $\geq$ 4 at presentation;
3. Venous plasma admission glucose > 7.0 mmol/l;
4. Informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Factorieel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Placebo

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	10-07-2009
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum: 22-06-2009
Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

N/A