Ghrelin in coma

Gepubliceerd: 11-07-2018 Laatst bijgewerkt: 13-12-2022

Ghrelin administration in comatose patients after cardiac arrest is safe, causes no serious adverse events relatable to ghrelin use and it improves functional recovery in these patients.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20553

Bron
NTR

Verkorte titel
GRECO

Aandoening

Postanoxic encephalopathy, postanoxic, coma after cardiac arrest, ghrelin administration, neuroprotection

Ondersteuning

Primaire sponsor: University of Twente
Clinical neurophysiology
Drienerlolaan 5
7522NB Enschede
Overige ondersteuning: ZonMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

We aim to measure safety and efficacy of intravenous treatment with acyl-ghrelin to promote

cerebral recovery in comatose patients after cardiac arrest. Safety will be monitored throughout hospitalization and during follow-up using all AEs reported, and by interim analyses by an independent DSMB. Efficacy will be measured by the primary outcome measure, i.e. functional recovery as measured by the Cerebral Performance Category (CPC) scale at six months after cardiac arrest.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Approximately half of all comatose patients after cardiac never regains consciousness because of severe postanoxic encephalopathy. The other half may be left with cognitive or motor disturbances. Currently, there is no treatment to promote cerebral recovery. Treatment with acyl-ghrelin improved functional recovery under experimental in vivo and in vitro conditions, and decreased histologically measured neuronal damage. Ghrelin has been tested in over one hundred human studies, including studies in healthy volunteers and patients with cardiopulmonary diseases, neuro-endocrine diseases, psychiatric diseases, and neurodegenerative diseases. Serious adverse events were extremely rare and difficult to attribute to ghrelin administration

Objective: First, we aim to estimate safety and efficacy of intravenous treatment with acyl-ghrelin to promote cerebral recovery in comatose patients after cardiac arrest. Second, we will estimate efficacy of ghrelin to modify case fatality, time to awaken, long term (cognitive) outcome, and cardiovascular outcomes, including blood pressure, treatment with inotropic medication, treatment with vasopression and cardiac biomarkers.

Study design: This will be a phase 2 multicenter, double blind, placebo controlled randomized clinical trial.

Study population: Comatose patients (GCS score of 8 or lower) after cardiac arrest and successful cardiopulmonary resuscitation, admitted to intensive care units of participating hospitals, will be included within 12 hours after resuscitation.

Intervention Intravenous treatment with acylated ghrelin 600micrg twice daily for 1 week vs. placebo.

Main study parameters/endpoints: The primary outcome measure will be functional outcome as expressed as the score of the cerebral performance category (CPC) at 6 months.

Doel van het onderzoek

Ghrelin administration in comatose patients after cardiac arrest is safe, causes no serious adverse events relatable to ghrelin use and it improves functional recovery in these patients.

Onderzoeksopzet

Case fatality

Time to awaken

Cardiovasculair measures: day 0-7

Venous blood samples: day 0, 1, 2, 3

CPC scores: after 3 en 6 months

Neuropsychological examination: after 12 months

Gastric residual volume: day 0-7

Onderzoeksproduct en/of interventie

Intravenous treatment with acylated ghrelin 600micrg twice daily for 1 week vs. placebo.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study a subject must meet the following criteria:

- Age ≥18 years

- Out of hospital cardiac arrest

- Successful cardiopulmonary resuscitation

- Return of spontaneous circulation ¡Ü12 hours ago

- GCS score on admission ≤ 8 or suspected coma in patients who are sedated

- Admission to intensive care unit

- Hemodynamic and respiratory stability as determined by the treating intensive care physician, with the minimum requirement of mean arterial pressure > 65 mmHg. Treatment with inotropes, vasopressors or IABP is allowed.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- Age <18 years

- A known progressive neurological disease

- Expected death within 48 hours

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-10-2018
Aantal proefpersonen:	160
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL7155
NTR-old	NTR7354

Register	ID
Ander register	ZonMW : 951 05001

Resultaten