Hydrocortisone as co-treatment to prevent neuropsychiatric adverse effects of dexamethasone.

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Co-treatment with a physiological dose of hydrocortisone will prevent or reduce neuropsychiatric adverse effects caused by dexamethasone.

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

Samenvatting

ID

NL-OMON22627

Bron
Nationaal Trial Register

Verkorte titel
DEXA-CORT

Aandoening

anxiety, depression, mania, delirium, sleep, cognition

Ondersteuning

Primaire sponsor: Leiden Univeristy Medical Center (LUMC)
Overige ondersteuning: ZonMw, Hersenstichting

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary parameter is neuropsychiatric adverse effects measured by the Brief Psychiatric

Rating Scale (BPRS).

Toelichting onderzoek

Achtergrond van het onderzoek

Over 800.000 individuals are treated annually in The Netherlands with synthetic glucocorticoids like dexamethasone. These drugs are life-saving but induce significant neuropsychiatric complaints in thousands of patients. Dexamethasone acts only via glucocorticoid receptors (GRs), while the endogenous hormone hydrocortisone stimulates in brain also mineralocorticoid receptors (MRs). An unwanted side effect of dexamethasone is the strong suppression of hydrocortisone levels. This depletes brain MRs from ligand, which is known to compromise brain function. We hypothesize that co-treatment with a physiological dose of hydrocortisone will re-fill brain MRs and prevent - or strongly reduce - psychopathology caused by synthetic glucocorticoids.

Doel van het onderzoek

Co-treatment with a physiological dose of hydrocortisone will prevent or reduce neuropsychiatric adverse effects caused by dexamethasone.

Onderzoeksopzet

This study has 8 to 10 timepoints in which different questionnaires, interviews, cognitive tests will be performed. Burden is approximately 5 to 6 hours.

Onderzoeksproduct en/of interventie

Hydrocortisone or placebo as add-on to dexamethasone.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Cranial glioma or meningioma scheduled to undergo surgery (resection)
- Minimal dose of peri-operative cumulative dexamethasone exposure of 24mg or more in 6 days
- ≥18 years
- Good clinical condition; KPS≥70
- Life expectancy ≥6 months

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Non-native speakers of Dutch or insufficient command of the Dutch language
- Patients that are unable to overview consequences of trial participation
- Patients with severe aphasia
- Patients that are not able to fill in the questionnaires because of cognitive impairments at the discretion of the physician
- Patients with psychiatric diseases or neurological deficits that interfere with the study to the judgement of treating physician

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd

Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-04-2019
Aantal proefpersonen:	180
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Toelichting
The datasets generated and/or analysed during the current study will be available in a repository with a persistent identifier after publication of the final results.

Ethische beoordeling

Positief advies

Datum:	04-01-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 54782
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6726
NTR-old	NTR6937
Ander register	ZonMw : 2017-003705-17 // 40-41200-98-9291
CCMO	NL63350.058.18
OMON	NL-OMON54782

Resultaten

Samenvatting resultaten

Regardless of the outcome, trial results will be submitted for publication in a peer-reviewed journal and presented at conferences.