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

Published: 04-01-2018
Last updated: 17-02-2025

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

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22627

Source
Nationaal Trial Register

Brief title
DEXA-CORT

Health condition

anxiety, depression, mania, delirium, sleep, cognition

Sponsors and support

Primary sponsor: Leiden Univeristy Medical Center (LUMC)
Source(s) of monetary or material Support: ZonMw, Hersenstichting

Intervention

Outcome measures

Primary outcome

The primary parameter is neuropsychiatric adverse effects measured by the Brief Psychiatric Rating Scale (BPRS).

Secondary outcome

Secondary parameters are neuropsychiatric adverse effects measured with different questionnaires (Hospital Anxiety and Depression Scale, Altman Self-Rating Mania scale and Positive Affect Negative Affect Scale); neurophysiological functioning assessed with different cognitive tests, sleep quality measured with actigraphy and the Leeds Sleep Evaluation Questionnaire (LSEQ) and quality of life with QLQ-C30+BN20.

Study description

Background summary

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.

Study objective

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

Study design

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

Intervention

Hydrocortisone or placebo as add-on to dexamethasone.

Contacts

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Eligibility criteria

Inclusion criteria

- 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

Exclusion criteria

- 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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2019
Enrollment:	180
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
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.

Ethics review

Positive opinion

Date:	04-01-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 54782
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6726

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

Study results

Summary results

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