Hypothalamic serotonin transporters in subjects suspect for hypothalamic damage

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To investigate if there are differences in serotonin transporters in the hypothalamus between subjects with hypopituitarism suspect for hypothalamic damage, subjects with hypopituitarism and no suspicion of hypothalamic damage and healthy age- and...

Ethical review	Approved WMO
Status	Pending
Health condition type	Hypothalamus and pituitary gland disorders
Study type	Observational invasive

Summary

ID

NL-OMON36631

Source
ToetsingOnline

Brief title
HypS-study

Condition

- Hypothalamus and pituitary gland disorders

Synonym
hypothalamic damage, hypothalamic dysfunction

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: FP-CIT SPECT, hypothalamic damage, hypothalamus, serotonin transporters

Outcome measures

Primary outcome

Difference in binding ratio in the hypothalamus of the radioligand [123I]FP-CIT

to serotonin transporters between subjects with pituitary insufficiency and

clinical suspect for hypothalamic damage, subjects with hypopituitarism without

suspicion of hypothalamic damage and healthy age- and gender matched controls.

Secondary outcome

To define the optimal time-point of assessing central serotonin transporter

binding with FP-CIT SPECT after injection of the radiotracer.

Study description

Background summary

Pituitary insufficiency is associated with sleep disturbances, metabolic abnormalities and a decreased quality of life despite proper hormonal substitution. The pituitary is both anatomically and functionally closely related to the hypothalamus, a highly organized part of the brain that plays a crucial role in many homeostatic processes including sleep-wake rhythm, energy metabolism, body temperature regulation and activity of the autonomic nervous system. Because the disorders associated with pituitary insufficiency show many similarities with the diverse functions of the hypothalamus, hypothalamic dysfunction may be involved in the pathophysiology of these disorders. Until recently, no diagnostic tools have been available to confirm hypothalamic dysfunction in these patients.
Recent developments in radionucleotide imaging of brain have enabled visualisation of serotonine transport in the human hypothalamus in vivo. Serotonin plays a very important role in the regulation of the hypothalamic functions. We hypothesize that patients suffering from hypothalamic dysfunction may also have a hyposerotonergic neurotransmission.
Therefore, we will investigate if there are differences in serotonin transporters in the hypothalamus between subjects with hypopituitarism and

clinical suspicion of hypothalamic dysfunction, subjects with hypopituitarism but without suspicion of hypothalamic dysfunction and healthy age- and gender-matched controls.

Study objective

To investigate if there are differences in serotonin transporters in the hypothalamus between subjects with hypopituitarism suspect for hypothalamic damage, subjects with hypopituitarism and no suspicion of hypothalamic damage and healthy age- and gender-matched controls.

Study design

Cross-sectional case-control study

Study burden and risks

Subjects will visit the research unit twice. During the first visit every potential participant will be screened for in- and exclusion criteria and instructed to fill out four validated neuropsychiatric questionnaires. The day before the SPECT scan all subjects will take 2 x 100 mg potassium iodide tablets p.o.
In the morning of the second visit, all subjects receive 100 mg potassium iodide tablets p.o. and a urine pregnancy test will be performed in all premenopausal females. Thereafter a catheter will be placed in an antecubital vein for respectively blood sampling (maximum volume will not exceed 75mL) and administration of the radioligand [123I]FP-CIT. At 1, 2 and 3 hours after administering, a SPECT brain scan will be performed which takes about 40 minutes each, during which the participant lies down on his back on the gamma camera bed. The radioligand [123I]FP-CIT has a European (CPMP) registration. In the trials preceding the marketing authorization it has been shown that no serious side effects occur after administration of this radioligand.
As the dose equivalent per [123I]FP-CIT injection amounts to 2.7 mSv, the total dose equivalent of the participant subjects will amount less than 10.0 mSv (WHO category IIb). For careful analyses of the SPECT scan, a MRI of the brain will be performed on the same day, requiring lying as still as possible for 20 minutes.

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

having pituitary insufficiency and suspicion of hypothalamic damage
or having pituitary insufficiency and no suspicion of hypothalamic damage
or (in case of controls) being healthy
age between 18-75 years old

Exclusion criteria

*Unwilling or unable to provide informed consent
*Serious neuropsychiatric problems
*Use of medication which interferes with serotonin metabolism (e.g. psychotropic medication like SSRIs or other antidepressants) and dopamin metabolism
*Life-time ecstasy, amphetamine or cocaine use
*Intravenous drug abuse
*Participation in another study associated with exposure to ionizing radiation during the last 12 months
*Pregnancy
*Contra-indication for MRI

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-07-2010
Enrollment:	18
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL32385.018.10