Hypothalame serotonine transsporters in mensen verdacht voor hypothalame schade.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20258

Source
NTR

Brief title
HypS-Study

Health condition

hypothalamic dysfunction
hypothalamic damage
pituitary insufficiency

hypothalame schade
hypothalame dysfunctie
hypofyse-insufficientie

Sponsors and support

Primary sponsor: Academic Medical Center, Amsterdam
Meibergdreef 9
1105 AZ Amsterdam
Source(s) of monetary or material Support: Academic Medical Center, Amsterdam

Intervention

Outcome measures

Primary outcome

Differences in binding ratio (hypothalamus to occipital cortex/cerebellum) of the radioligand [123I]FP-CIT to serotonin transporters in the hypothalamus in subjects with hypopituitarism and clinical suspicion of hypothalamic dysfunction compared to subjects with pituitary insufficiency but no clinical suspicion of hypothalamic damage and healthy age- and gender-matched controls.

Secondary outcome

The optimal time-point to assess 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 serotonin 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 have a hyposerotonergic neurotransmission.

Therefore, we will investigate if there are differences in serotonin transporters in the hypothalamus in subjects with hypopituitarism and clinical suspicion of hypothalamic dysfunction compared to subjects with pituitary insufficiency but no clinical suspicion of hypothalamic damage and healthy age- and gender-matched controls.

Study objective

We hypothesize that subjects suffering from hypothalamic dysfunction may have a hyposerotonergic neurotransmission. Therefore we will investigate if there are differences in specific hypothalamic-to-nonspecific [123I]FP-CIT binding ratios using SPECT in subjects with hypopituitarism and clinical suspicion of hypothalamic dysfunction compared to subjects with pituitary insufficiency but no clinical suspicion of hypothalamic damage and healthy age- and gender-matched controls.

Study design

1, 2 and 3 hours after administering of approximately 110 MBq [123I]FP-CIT.

Intervention

N/A

Contacts

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Eligibility criteria

Inclusion criteria

1. Having pituitary insufficiency and suspicion of hypothalamic damage OR having pituitary insufficiency without suspicion of hypothalamic damage OR (in case of controls) being healthy;

2. Age between 18-75 years old.

Exclusion criteria

1. Unwilling or unable to provide informed consent;

2. Serious neuropsychiatric problems;

3. Use of medication which interferes with serotonin metabolism (e.g. psychotropic medication like SSRIs or other antidepressants) and dopamin metabolism;

4. Life-time ecstasy, amphetamine or cocaine use;

5. Intravenous drug abuse;

6. Participation in another study associated with exposure to ionizinf radiation during the last 12 months;

7. Pregnancy;

8. Contra-indications for MRI.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	22-09-2010
Enrollment:	18
Type:	Anticipated

Ethics review

Positive opinion
Date: 17-09-2010
Application type: First submission

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
NTR-new	NL2412
NTR-old	NTR2520
Other	METC AMC : 10/132
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A