Brain development, brain functioning, growth and metabolic aspects in the clinical management of transsexual adolescents.

Gepubliceerd: 10-01-2007 Laatst bijgewerkt: 18-08-2022

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

Samenvatting

ID

NL-OMON26605

Bron
NTR

Verkorte titel
clinical study on transsexual adolescents

Aandoening

Transsexuality according to the DSM IV criteria.

Ondersteuning

Primaire sponsor: VU university medical center
Overige ondersteuning: Ferring Pharmaceuticals Denmark

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Cognition: performance and reaction time on three cognition tasks (verbal fluency task, mental rotation task and emotional faces task), reaction times and performance will be measured;
2. Functional MRI: data during the verbal fluency task, mental rotation task and emotional faces task;
3. Structural MRI: data on total brain volume, gray and white matter (amount and percentage), CSF, volume frontal and temporal lobe, gyrification, brain asymmetry. ROI analysis of basal ganglia, amygdala, hippocampus, corpus callosum, hypothalamus.

Toelichting onderzoek

Achtergrond van het onderzoek

The present study will focus on the consequences of long-term delay of puberty induced by treatment with Decapeptyl-CR. We will investigate the effects of this treatment in regard to brain functioning, brain development, various endocrine, metabolic and anthropometric aspects before, during and after treatment with Decapeptyl-CR alone and in combination with cross-sex hormones in juvenile transsexuals. Hereby we will focus on sex differences between transsexual adolescents and similar aged individuals of both sexes by investigating brain development and brain functioning, as well as on possible determinants of the aetiology of transsexuality by means of structural and functional MRI and family pedigree research.

Doel van het onderzoek

The hypothesis of this study is that the pubertal delay in transsexual adolescents, induced by treatment with GnRH analogues, will cause a difference in the development of brain structures and brain function between transsexuals and age matched control subjects without transsexuality. If cross-sex hormones are added from the age of sixteen, a catch up of brain development is expected. It is of great interest to investigate if this brain development will occur in the direction of the biologic or desired sex.
Gender dysphoria is associated with atypical levels of sex hormones during pregnancy. The hypothesis of this study is that already at a young age, development of brain structures and brain function in gender dysphoric children will occur in the direction of the desired instead of the biologic sex.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Patients: measurements will be performed at a prepubertal stage, before start of GNrH analogue Triptoreline/ Decapeptyl-CR (current puberty delaying medication for transsexual adolescents in the VUmc from the age of 12 and if puberty has already started i.e. Tanner stage B2 in girls, G1-2 in boys), before start of cross-sex hormones (17 beta oestradiol in male-to-female transsexuals and sustanon in female-to-male transsexuals), one year after start of cross-sex hormones and 1-2 years after gender reassignment surgery.

Age matched control subjects (friends of the transsexual patients): measurements will be performed if the transsexual friend starts with puberty delaying treatment, if the transsexual friend starts with cross-sex hormones and 1-2 years after surgery of the transsexual friend.

Interventions:

1. Structural MRI, method used: voxel based morphometry, ROI analysis;

2. Functional MRI (BOLD) during which 3 cognition tasks will be performed (mental rotation, verbal fluency and emotional faces);

3. Physical examination with anthropometric measurements and gathering of information about pubertal stage according to Tanner;

4. Digital photographs and physical appearance list;

5. Salivary testosterone measurements;

6. Family pedigree research: homosexuality/ transsexuality in family.

The duration of the intervention will be approximately three hours for every visit, which means at maximum 5 visits (if patients will be followed longitudinally) for the patients and three visits (if control subjects will be followed longitudinally) for the control subjects.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Inclusion criteria pubertal patients:

1. Girls and boys with transsexualism who are eligible for sex reassignment according to psychologist and psychiatrist (If they are older than 12 years, psychologically stable and live in a stable social environment);

2. Girls have to be in stage B2 and boys in G2-G3 with measurable estradiol and testosterone levels respectively;

Inclusion criteria pre-pubertal patients:

1. Girls and boys with high probability of transsexualism according to psychologist or psychiatrist and the age of 9-12 years;

2. Girls have to be in an earlier stage than B2 and boys in an earlier stage than G2-G3;

Inclusion criteria healthy subjects:

1. Girls and boys who are similar aged friends of the transsexual patients.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Exclusion criteria patients:

1. Intersex conditions;

Exclusion criteria healthy subjects:

1. Puberty delaying treatment or hormonal therapy; oral anticonception users are not excluded.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-02-2007
Aantal proefpersonen:	264
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	NL854
NTR-old	NTR868
Ander register	:
ISRCTN	ISRCTN81574253

Resultaten

Samenvatting resultaten

Delemarre-van de Waal HA, Cohen-Kettenis PT. Clinical management of gender identity disorder in adolescents: a protocol on psychological and paediatric endocrinology aspects.Eur J Endocrinol. 2006 Nov;155 Suppl 1:S131-7.