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

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Ethical review	Approved WMO
Status	Pending
Health condition type	Psychiatric disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON30547

Source
ToetsingOnline

Brief title
clinical study on transsexual adolescents

Condition

- Psychiatric disorders NEC

Synonym
gender identity disorder, transsexuality

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: Ferring,Ferring Pharmaceuticals

Intervention

Keyword: adolescence, brain, development, transsexuality

Outcome measures

Primary outcome

* Cognition: performance and reaction time on three cognition tasks (verbal fluency task, mental rotation task and emotional faces task)

* Functional MRI: data during the verbal fluency task, mental rotation task and emotional faces task.

* 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

Secondary outcome

* score from -10 to 10 on handedness questionairre

* performance score on adapted WISC-III questionairre (4 items: 2 performance, 2 verbal)

* information about psychological functioning (parent questionairre)

* anthropometric data, information about pubertal stage according to Tanner

* information about homosexuality/ transsexuality in familymembers

* digital photographs and physical appearance list (14 items)

Study description

Background summary

The clinical management of transsexual adolescents of the VUmc consists of suppression of puberty with GnRH analogues from the moment the juvenile transsexuals reach pubertal stage 2 according to Tanner. From the age of 16 they receive cross-sex hormones in addition to the puberty delaying medication. Treatment at this age and the use of GnRH agonists as a diagnostic aid is still controversial. Knowing more about the effect of hormone treatment is not only of theoretical interest but also of very great clinical relevance. The hypothesis of this study is that brain functioning and brain structure of transsexual teenagers treated with GnRH agonists is according healthy individuals without transsexuality.
Little is known about etiological aspects of transsexuality. Transsexuality is associated with atypical sex hormone levels during pregnancy. The hypothesis is that in transsexualism the development of brain structures and brain functioning is in the direction of the desired sex instead of the biological sex.
The VUmc gender team for children and adolescents assesses early-onset transsexuals on a regular basis. This group is unique since, according to their parents, these transsexual children and adolescents did never show gender related behaviour corresponding with their biological sex, neither did they use cross-sex hormones, which might be influential on their brain development. We therefore believe that the best chances to find biological differences in brain development and function between transsexuals and non-transsexual are in this group. As the VUmc assesses by far the largest number of transsexual adolescents in the world, we are in a unique position to generate findings that may give us insight in the aetiology of the phenomenon and the effects of these pituary agonists on brain development

Study objective

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.

Study design

This study is an observational, non invasive cross-sectional (with longitudinal

continuation) prospective follow-up study.

Study burden and risks

There are no risks.
We use MR imaging, which is a non-invasive technique, there is no potential harm from radiation. We measure salivary testosterone instead of blood samples which is less invasive. All investigations will take place on the same day to minimize the effort for the subjects. We practise the cognition tasks in advance to reduce the stress of the subjects during scanning. We provide video, audio and photo material and s dummy scanner will be available to prepare the subjects for the MRI-scanner. If the extend of the burden is too much, the scanning will not be continued.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)

Children (2-11 years)

Inclusion criteria

Inclusion criteria pubertal patients: 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) . Girls have to be in stage B2 and boys in G2-G3 with measurable estradiol and testosterone levels respectively.
Inclusion criteria pre-pubertal patients: girls and boys with high probability of transsexualism according to psychologist or psychiatrist and the age of 9-12 years. Girls have to be in an earlier stage than B2 and boys in an earlier stage than G2-G3.
Inclusion criteria healthy subjects: girls and boys who are similar aged friends of transsexual patients

Exclusion criteria

Exclusion criteria patients: intersex conditions
Exclusion criteria healthy subjects: puberty delaying treatment or hormonal therapy, oral anticonception users are not excluded

Study design

Design

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

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2007
Enrollment:	244
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	NL15404.029.06