Early Mental Response - The EMRE Study

[NCT ID not yet assigned]

Protocol ID: 2019-004349-34 SE

Informed Consent Form

Information to research persons

This information is directed to patients that recently established the diagnosis gender dysphoria and you are here by being asked for participation in this study. Before you decide if you want to participate, please read the information below. You are most welcome to ask questions if anything is unclear.

Background

Gender dysphoria is a condition that is characterized by incongruence between a person's gender identity and the gender assigned at birth. This condition has been treated for nearly 50 years with hormonal treatment and surgery to verify the gender identity by changing hormonal levels and the body to be more congruent with the perceived gender. The goal with this treatment is to reduce the gender dysphoria and a large number of follow up studies confirm large patient satisfaction with the treatment and an increase in quality of life. After treatment is initiated a slow change of the body is induced and typical features appears such as change of skin quality, thickness of subcutaneous fat, acne, hair growth on body and head, depth of voice etcetera. We know that these hormones affect the brain, and that temper and emotions are altered. A clinical observation is that, for some individuals, the effects on the brain occurs much more rapidly (within a few weeks) compared to the bodily changes and that these effects often are regarded as very positive. Some of these effects are previously known, such as changes in emotional response and sexual desire, but others are vaguer, and more or less undescribed in the medical literature.

Goal

The goal is to explore the rapid psychiatric effects to a greater extent that arise during hormonal treatment of transgender men, and to distinguish them from placebo as well as psychiatric effects from social transitioning.

Enquiry for participation

70 trans men with recently diagnosed gender dysphoria will be asked for participation. Examination/filling out forms will occur during 3 occasions: Right before start of medical treatment, after 2 weeks and after 6 weeks from the start of the study. Blood samples are withdrawn before study start and after 6 weeks. The head researcher for this project is Region Stockholm. Head researcher refers to the organization responsible for the study.

How is the study performed?

The study consists of 2 visits here at ANOVA, Norra Stationsgatan 69 in Stockholm. You will be asked about participation from your treating physician and if you are interested you will receive this research person information. After reading the form and consenting to participation you will be

summoned to an appointment at ANOVA. You will be able to ask questions and sign the informed consent form and meet a doctor specialized in hormonal treatments for a general examination. At both visits you will be asked to fill out 8 forms regarding self-esteem, sexual desire, depressive symptoms/anxiety, emotional reactivity, aggression, quality of life, impulsiveness and gender dysphoria and submit blood samples to assess hormonal levels. You will also be asked about which treatment you believe that you have/are received/receiving and if you experience that social transitioning has begun. You will fill out the same questionnaires online after two weeks of treatment.

The total amount of blood subtracted during the study amounts to 35ml, in comparison a normal blood donation amounts to 400-500ml.

Blood tests and examinations are performed according to the following Schedule:

	Screening	Start	2 weeks online	6 weeks Visit 2
Doctors visit	X			X
Questionnaire		X	X	X
Blood work	X			X
Weight and height	X			X
Blood pressure	X			X

When the study ends after 6 weeks all participants will receive treatment according to clinical routine with intramuscular testosterone (Nebido®).

Treatment

This is a double-blind randomized study which means that neither you or the caregiver treating you know if you receive injection with testosterone or placebo (non-active treatment). Which treatment you receive at the first visit is determined by chance. During the visit at 6 weeks the randomization ends (you will be informed which treatment you were given) and all participants receive testosterone (Nebido® 1000mg/4ml) in standard dosing. For the participants that received testosterone during first visit this will be the second injection which is fully in accordance with clinical routine. For the participants that received placebo initially this will be the first injection with testosterone, and they will receive the second shot at their health care center after 6 weeks. Testosterone is administered by intramuscular injection in the buttocks.

Time Schedule

At the first visit you should account for approximately 1 hour for the visit with your physician and blood work, at the second visit you should account for about 1 hour to fill out the forms, and approximately 20 minutes for the injection. That equals about 2 hours and 20 minutes. After two

weeks you should account for about 1 hour to fill out the forms online, and at the last visit you should account for 1,5 hours in total for the questionnaires and a new injection.

All blood work and contact with your physician is free of charge.

Risks

The risks associated with regular blood tests are very low but can induce discomfort in conjunction with the needlestick and can produce a hematoma afterwards. If desired, we provide numbing cream.

Testosterone- or the placebo injection is given at a very slow rate in the muscular part of the buttocks and could in rare cases be perceived as painful. In rare cases it could produce a slight cough that passes quickly. The cough is not dangerous and pass within the hour. Placebo is manufactured under controlled forms and does not contain any active substance. There for there are no further risks with placebo treatment other than the small risks presented above associated with the injection in its own.

Pregnancy

Testosterone treatment is damaging to the fetus and is there for not allowed during pregnancy. If you have had unprotected sex with your partner and conditions are present that pregnancy is possible a negative pregnancy test is required for participation. If unprotected sex with a partner that can lead to a pregnancy is practiced approved contraceptive barrier method is required.

1.1. What happens to my data?

The project will collect and register information about you.

During the study we will gather information such as date of birth, treatment, information regarding health (such as previous and current diseases) and results from the bloodwork and questionnaires conducted during the study. Patient data from the study will be processed in a database and stored in a register for 15 years. Your data is protected under law and no unauthorized personnel have access to the register. When processing data your name and personal number will be replaced with a code anonymizing all participants. Only the study supervisor will have access to the ”code key”. When data from the study eventually is published, it will be impossible to disclose a participant’s identity. The study supervisor is entrusted to handle the personal information accordingly. You will be informed of your own results as well as the results of the entire group (in an anonymized form).

For data verification authorized representatives from Region Stockholm, as well as relevant government institutions, can demand parts of medical- or study journals tied to the study (including your medical history).

Your answers and your results will be managed so that no one without authorization can access them. Region Stockholm is responsible for your personal information. According to the European union data protection regulation you have the right to access all information concerning you in the project without cost, and upon the occurrence, have faulty information corrected. You could also

demand that personal data is erased or restrict access to it. The right to erase data and to restrict access to data does not apply if the data is essential for the ongoing research. If you want to access personal data you are asked to establish contact with principal researcher Mats Holmberg, tel 08-517 73 200. E-mail: mats.holmberg.1@ki.se. “Dataskyddsombud” are accessed through Dataskyddsombudet, 17176 Stockholm, Tel: 08-5858000, E-mail: Dataskyddsombud.karolinska@sll.se. If you experience that the contact exchange with Karolinska Sjukhuset is insufficient or faulty, you are welcome to contact the authority of integrity protection ”Integritetsskyddsmyndigheten” (former Datainspektionen) with a complaint regarding Karolinska sjukhuset’s handling of personal data, tel 08-657 61 00. E-post: imy@imy.se.

1.2. What happens to my test results?

All the blood samples mentioned above and the answers of the questionnaires will be encoded (pseudonymized) and can there for not be connected to you as individual. The code key will be kept at ANOVA, Karolinska Sjukhuset, in a locked safe storage. The code key is kept in a way making it inaccessible for unauthorized personnel. The blood samples are analyzed within six months upon withdrawal and are destroyed immediately after analyzation.

1.3. How do I receive information regarding results?

The results from the study will be published in international medical journals in such a form that makes individual results impossible to identify. You do not have to take part of your own results if you do not want to. If unexpected findings occur in your blood work this will be addressed within the regular health care at Karolinska University Hospital.

What happens if I want to quit?

Participation is entirely voluntary, and if you choose not to participate or withdraw from the study it will not affect your given healthcare in any way. As patient you are able to refrain from parts of the study. You can contact us at any point and inform that you choose to withdraw from the study, the decision will not affect future healthcare in any way.

Ethics

The study is approved by the ethics committee (“Etikprövningsmyndigheten”) with registration number (”diarienummer”) 2022-03016-01

Insurance

All participants are covered by the patient injury insurance (”patientskadeförsäkringen”).

Medical responsibility, more information

If you desire more information, please contact most responsible physician:
Överläkare Mats Holmberg
ANOVA, Karolinska Universitetssjukhuset, Norra Stationsgatan 69, 171 76 Stockholm. Tel: 08-517 73 200.

Informed consent

I have verbally been informed of the study and taken part in the written information above. I am aware that my participation in this study is entirely voluntary and that I can withdraw from the study at any time without further notification. The decision to withdraw will not affect the healthcare provided in any way or form. a) I have been given time to ask questions and I have had them answered. b) I give my consent to participate in the study. c) I consent to that personal data is handled in the way described in this document.

I confirm that I have been given information about testosterone and the damaging effects to a fetus during pregnancy and that I am not pregnant. I confirm that an approved contraceptive barrier method is required if sex with a cis male is practiced.

City/Province/postal area:_____Date:_____

Name:_____Name clarification:_____

I confirm that the research person has received verbal and written information regarding the study and has been given time to ask questions.

City/Province/postal area:_____Date:_____

Name:_____Name clarification:_____