



Young Person Information Sheet

This is a study looking at the effect of blocking sex hormones in early puberty. The treatment will be offered only to young people who meet certain requirements as described below.

Study Title: An evaluation of early pubertal suppression in a carefully selected group of adolescents with Gender Identity Disorder

We understand that you are interested in taking part in this research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Take time to read this information sheet carefully, and discuss it with others if you wish. Please ask us if anything is unclear, or if you would like more information. Take as much time as you need to decide whether or not you wish to take part.

Why are we doing this study?

Many young people who are unhappy with their biological gender find the changes in their body during their teens distressing. Some countries now offer treatment to stop some of these physical changes and give young people time to think about their gender identity.

The treatment given is a hormone blocker which stops the body's natural sex hormones. These sex hormones are called testosterone in biological boys and oestrogen in biological girls.

We are carrying out this study because there is not much evidence (scientific information) on the use of hormone blockers in young people. We aim to:

- Look at the effects of blocking sex hormones in young people aged 12-15, and
- Find out if young people taking part in the study feel satisfied and better about themselves following this treatment

By collecting this information, we also hope to improve how we help other young people and to give information to other professionals such as doctors, teachers and psychologists.

Who can take part in the study?

You may be able to take part if:

- You have a strong feeling that you are in the wrong body or that your gender and body do not match. Doctors call this a "Gender Identity Disorder" and they have agreed on a list of feelings and behaviours which young people with this condition show.
- Your body is starting to change- this is called early puberty. To check that your body is at this stage, you will need to have some medical tests and be physically examined

by a doctor who specialises on the effect of hormones in young people.

- Being in puberty has made you more distressed and you want treatment to stop your body changing further.
- Your parents/carers are supportive of your wish to have hormone blockers in early puberty.
- The person/s you see at the Tavistock Centre have completed their assessment together with you and believe that you are suitable and ready to take part in the study.

Once the assessment at the Tavistock has taken place and physical examination and tests have been done, it can be decided whether you are able to take part in the study. If you are not able to take part at this time, we will explain the reasons for this decision and discuss this with you and your parents/carer.

Why do I need a physical examination and other medical tests?

We need to make sure that your body is in early puberty, that you are physically fit for hormone blockers and that you don't have any other medical condition that could affect this treatment.

The examination will be carried out sensitively and the doctor will explain what they are going to do beforehand. You will be able to discuss any concerns or worries that you might have.

The medical tests will include blood tests, a scan to look at your bone density, and an ultrasound scan of the womb and ovaries in girls. The doctor will explain what each test involves beforehand.

Do I have to take part?

Once it has been decided that you are able to take part in the study it is up to you to decide whether or not you want to go ahead. Even if you decide to take part in the study, you are free to change your mind at any time without giving a reason. Deciding not to take part will not affect the usual treatment you receive at the Tavistock.

If I decide to take part, what happens next?

We will ask you and your parent/carer to sign a form to say that you agree to take part in this study and that you understand the possible benefits and risks of taking part (as described in the section below).

You will then start hormone blocker treatment. At first this will involve monthly injections given at the Endocrine Clinic (Hormone Clinic) at University College London Hospital (UCLH). This may become 3-monthly later on in the treatment. The doctor will see you regularly to check the effects of the treatment (every 3 months for the first year, then every 6 months until you are 16).

You will need to meet the usual person you see at the Tavistock Centre at least once every 3 months and a member of the research study team every 6 months. These meetings are there to support you, to talk about how the treatment affects how you are feeling and to check that you wish to continue with the treatment. We will ask your permission to tape record the 6-monthly interview with a member of the research team and if we use written quotes from any of these interviews they will be anonymised (this means we that you will not be recognisable). We will also ask you and your parent/carer to complete some questionnaires once a year until you are 16.

The research will finish once you turn 16 but you will continue with the usual treatment that the young people and their families receive at the Tavistock and UCLH.

What are the possible benefits of taking part?

We have looked at other countries who have given this treatment and the results suggest that:

1. Hormone blockers which block the body's natural sex hormones may improve the development of your body in your desired gender. They may also improve the way you feel about yourself.
2. If you decide to stop the hormone blockers early your physical development will return as usual in your biological gender. The hormone blockers will not harm your physical or psychological development.
3. Hormone blockers will make you feel less worried about growing up in the wrong body and will give you more time and space to think about your gender identity.
4. Hormone blockers may reduce the amount of operations that you may need as an adult (after the age of 18) should you wish to have operations to change your body.

What are the possible disadvantages and risks of taking part?

1. We do not know how hormone blockers will affect bone strength, the development of your sexual organs, body shape or your final adult height. There could be other long-term effects of hormone blockers in early puberty that we don't yet know about.
2. Hormone blockers could affect your memory, concentration and the way you feel. They can also affect how you feel about your gender and how likely you are to change your mind about your gender identity.
3. Hormone blockers could affect your ability to have a baby. It could take 6 to 12 months or longer after stopping the hormone blocker before boys start making sperm again or girls start maturing eggs in their ovaries.

Will information about me be kept private (confidential)?

If you decide to take part in the study, we will let your GP know and tell them about the treatment you are being offered. We will also let the people you have been seeing at your local Child and Adolescent Mental Health Service know. The information we collect about you during the study will be kept confidential. We will not give your name or address to anyone outside the clinic without asking you first.

What will happen to the findings of the study?

We will use the findings to look at the benefits and disadvantages of hormone blockers in young people with "gender identity disorder". We will present the results at meetings and publish them in scientific journals. We will not mention you personally in any report without asking you first. We will let you know about the results of the study if you wish.

Who has given us permission to carry out this study?

The Central London Research Ethics Committee 2 has approved the study.

Contact for further information

If you have any questions or would like more information about the study please contact:

Elin Skagerberg, Research Psychologist at the Tavistock Centre.

Tel: 020 8938 2130

Fax: 020 7794 1879

Email: eskagerberg@tavi-port.nhs.uk

Gender Identity Development Service

The Tavistock and Portman NHS Foundation Trust

Tavistock Centre

120 Belsize Lane

London NW3 5BA

Your parent/carer has been given a similar information sheet.

Thank you for taking the time to read this information sheet. Please think carefully about the advantages and disadvantages of taking part in the study before you decide.