Parent/carer Information Sheet

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

We understand that your child is interested in taking part in this research study. Before you and your child 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 your child to take part.

What is the purpose of the study?

Many young people with Gender Identity Disorder find the physical changes of puberty distressing. Some countries now offer treatment to pause puberty to prevent further physical development and give young people time to think about their gender identity.

The treatment given is a Gonadotropin-releasing hormone analogue (or hormone blocker, for short). Hormone blockers block the body's natural sex hormones (testosterone in boys and oestrogen in girls). If the hormone blocker is stopped, pubertal development can continue.

We are carrying out this study because there is little evidence about the benefits and possible risks of hormone blocker treatment in young people in early puberty. We aim to:

- Investigate the effects of blocking sex hormones in early puberty, and
- Assess the satisfaction and wellbeing of young people who take part in the study

By collecting this information, we also hope to improve our service for other young people and to provide information to professionals elsewhere.

Who can take part in the study?

Your child may be eligible for the study if:

- They have a diagnosis of Gender Identity Disorder. Some people describe this as a longstanding belief that they are in the wrong body or that their gender and body do not match.
- Your child is in early, established puberty. To check this, he/she will need a physical examination by one of the Paediatric Endocrinology doctors in the study team and some medical tests.
- Being in puberty has made your child more distressed and he/she wants treatment to stop puberty developing further.
- You support their request for blocker treatment in early puberty.
- Your child's key workers at the Tavistock Centre have completed their assessment together with you and your child and agree that he/she is eligible to enter the study.

Once the Tavistock assessment, physical examination and tests have been done, it can be decided whether your child is eligible for the study. If they are not eligible to take part at this time, we will explain the reasons for this decision and discuss this with you and your child.

Why are the physical examination and other medical tests necessary?

We need to make sure that your child is in early puberty, that they are physically fit for blocker treatment and that they don't have any other medical condition that could affect treatment.

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

The medical tests will include blood tests, a bone density scan, and a pelvic ultrasound scan in girls. We will explain what each test involves beforehand.

Does my child have to take part?

It is entirely up to you and your child whether or not he/she takes part. Even if your child decides to enter the study, they and you are free to change your minds at any time without giving a reason. Deciding not to take part will not affect the standard of care you receive.

What will happen to my child if he/she decides to take part?

We will ask you and your child to sign a consent form confirming that you wish to enter the study and that you understand the benefits and possible risks of taking part (described below).

Your child will then start hormone blocker treatment. This will involve monthly injections given at the Adolescent Endocrine Clinic at University College London Hospital (UCLH). A Paediatric Endocrinologist from the study team will review your child regularly to monitor the effects of treatment (every 3 months for the first year, then every 6 months until they are 16).

You will also need to meet your key worker at the Tavistock Centre every 3 months and a member of the study team every 6 months. These meetings are to support you and your child, to monitor the psychological effects of treatment and to check that your child wishes to continue with the treatment. We will also ask you and your child to complete several study questionnaires once a year until they are 16.

After your child exits the study at the age of 16, you will continue to see the Tavistock and UCLH gender identity teams and your child's treatment will continue as part of routine care.

What are the potential benefits of taking part?

Early results from similar studies in other countries suggest that:

1. Blocker treatment in early puberty may improve physical outcomes and psychological wellbeing during adolescence and adulthood;
2. Early blocker treatment is reversible and does not have harmful effects on physical or psychological development.
3. Early blocker treatment reduces anxiety in young people with Gender Identity Disorder and allows time and space to think about their gender identity.

What are the possible disadvantages and risks of taking part?

1. We do not know how blocker treatment in early puberty will affect bone strength, sex organ development or body shape in the long-term, or final adult height.
2. Blocker treatment could affect your child's memory, concentration and mood.
3. Blocker treatment in early puberty could influence your child's perceived gender identity and how likely they are to change their mind about their gender.
4. Blocker treatment could affect your child's fertility. It could take 6 to 12 months or longer after stopping the blocker before boys start making sperm again or girls start maturing eggs.
5. There could be other long-term effects of early blocker therapy that we don't know about.

Will information about my child be kept confidential?

If your child decides, with your support, to enter the study, we will let your GP know and tell them about the treatment your child is being offered. We will also let your local Child and Adolescent Mental Health Service know if applicable. The information we collect about your child during the study will be kept strictly confidential in accordance with the Data Protection Act, 1998. We will not give your child's name or address to anyone outside the clinic without your consent.

What will happen to the results of the study?

We will use the results to assess the benefits and disadvantages of early blocker treatment in young people with Gender Identity Disorder. We will present the results at professional meetings and publish them in scientific journals. We will not identify your child in any report without your consent. We will provide you with a summary of published results if you wish.

Who has reviewed the 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, please contact:

Elin Skagerberg, Research Psychologist at the Tavistock Centre.
Tel: +44 (0)20 8938 2130
Fax: +44 (0)20 7794 1879
Email: eskagerberg@tavi-port.nhs.uk

We have also given your child a copy of this information sheet.

Gender Identity Development Service
The Tavistock and Portman NHS Foundation Trust
Tavistock Centre
120 Belsize Lane
London NW3 5BA

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