The Tavistock and Portman NHS
NHS Foundation Trust

Freedom of Information Act 2000 disclosure log entry

Reference
18-19398

Date sent
14/06/2016

Subject
Paper on adolescents with Gender Identity Disorder"

Details of enquiry
Please supply copies of
1. Protocol
2. Participant Information Sheet: Parent/Carer Information Sheet
3. Participant Information Sheet: Young Person Information Sheet from the study "An evaluation of early pubertal suppression in a carefully selected group of adolescents with Gender Identity Disorder" (REC reference number 10/H0713/79), submitted to Central London REC 2 on 5 November 2010. This study later received the IRAS Project ID 38588.

Response Sent
The requested documents sent as attachments, and shown on the following pages are:
1. Early Intervention Research Protocol
2. Participant information sheet: parent/carer information sheet
3. Participant information sheet: young Person Information Sheet

Early Intervention Protocol

Protocol:

The design of the protocol should interfere as little as possible with the clinical model of care of the GIDS (treatment as usual). This involves carrying out the research at the two sites of the service: The GIDS Tavistock clinic and University College London Hospital (UCLH) for the paediatric and endocrinology components. This should allow for service users who wish to withdraw from the research protocol to continue to receive treatment as usual.

The system for monitoring outcomes should be manageable i.e. where possible, follow-up research appointments should be arranged to coincide with the administration of the analogue and follow-up physical investigations.

Participants will be recruited from the adolescents attending the Gender Identity Development Service. The entry criteria will be consistent with the protocol used at the Amsterdam Gender Clinic (Cohen-Kettenis & Delemarre-van De Waal, 2008; Delemarre-van De Waal & Cohen-Kettenis, 2006; De Vries et al., 2006). All adolescents and their families attending the service will receive information about this study included in the general information leaflet of the service. Adolescents and their parents who seek this treatment and meet the eligibility criteria will be considered for inclusion in the study. Young people and their families will receive information about this research project through a GIDS general information leaflet given to the service users at the beginning of their contact with the service. Young people (between the age of 12 and 15) and their families who have attended the service for at least 6 months and attended at least four interviews, who actively request intervention in early puberty, and who are deemed to meet the other psychosocial eligibility criteria by the treating clinician/s will be given further written information about the project.

If they meet the eligibility criteria they will be asked to fill in the following questionnaires if they have not already been fully completed within the last 3 months.

General Psychological Functioning
Child Behaviour Checklist
Youth Self Report
Teacher's Report Form
The Children's Global Assessment Scale (completed by the clinician)
Social Responsiveness Scale
Kidscreen52 (wellbeing questionnaire)

Gender Identity / Dysphoria
Gender Identity Interview
Utrecht Gender Dysphoria Scale
Body Image Scale
Recalled Childhood Gender Identity Scale
Dimensional DSM Criteria GID List

Endocrine evaluation
Young people meeting the psychosocial eligibility criteria will be offered a physical assessment at the UCLH site by the research paediatrician to determine the Tanner stage of pubertal development. Only young people who have reached the Tanner stage 2/3 of pubertal development will be eligible from the physical point of view. Young people at stage 3 or 4 would also be eligible. Informed consent will be sought from the adolescent and a legal guardian.

The following baseline investigations will be carried out at UCLH:

1. Karyotype (to confirm genetic make-up in terms of biological sex)
2. Baseline blood tests and hormone profile
3. Synacthen test in biological girls (to exclude congenital adrenal hyperplasia, a rare inherited endocrine condition)
4. Hand and wrist X-ray to check bony maturity (or 'bone age')
5. Dual X-ray absorptiometry (DXA) scan to check bone density (bone strength)
6. Pelvic ultrasound in biological females to check that the womb and ovaries are present – as we would expect -and appear normal

On the basis of this information the chief and principal investigators in consultation with the key clinicians will make a decision as to whether the criteria have been fulfilled and whether analogue treatment can be offered. The analogue treatment will be administered at UCLH where possible but may be delivered locally by appropriately trained individuals if required.

It is envisaged that approximately 10-15 young people per year will meet the eligibility criteria. It is expected that the project will be run for about 6 years and that the recruitment will stop after 3 years. The people who were recruited in the third year will then have enough time to complete the treatment with the hypothalamic blocker before returning to standard protocol outside the research study.

The study questionnaires will be administered on a yearly basis from the commencement of the analogue treatment until the age of 16. Young people and their families who agree to be involved in the study will also commit themselves to be seen for a clinical interview with their key clinician and a follow-up semi-structured interview by a member of the clinical research team once every 6 months until the age of 16 when they will become eligible to start cross-hormone treatment. The clinical interview will be managed in whatever way the therapist feels is appropriate. The aim of the semi-structured research interview will be to monitor the psychological effects of the analogue and the persistence of the gender identity disorder and the wish to continue with the treatment so that the data collected will be recorded in a standardised way. At the age of 16 after completing the project the young people will receive treatment within the standard protocol and continue to be monitored under the audit procedures of the service. All participants in the study will be encouraged to participate in the therapeutic program of the GIDS as deemed appropriate in discussion with the clinician involved. This could involve family work, individual work and network-liaison meetings with local services. These additional psychosocial interventions, which are part of the treatment as usual by the GIDS, will be carefully recorded as they may be useful for future single case studies regarding possible mechanisms contributing to particular outcomes.

There will be review appointments with the Paediatric Endocrinologist every 3 months for the first year and then biannually until the age of 16. These will include a physical examination to monitor the Tanner stage of pubertal development and other aspects of physical development, and to exclude other medical conditions. Safety monitoring will include evaluation of the following:
1. Linear growth, 3monthly
2. DXA scan, yearly, to check bone density
3. Blood hormone profile, 3monthly for the first year then biannually
4. Blood tests to check kidney and liver function, blood count, bone profile and vitamin D levels, 3monthly for the first year then biannually.

The progress of the treatment will be reviewed at least once every 6 months by the study steering group and by the research team and the clinical team at the regular clinical meetings of the GIDS. An early review can be called at any time by any member of the team.

At the end of the first three years the data will be analysed and an interim report will be produced giving a provisional evaluation in line with the objectives of the study. The final report will be produced at the end of the 6 years.

In designing the project the research group carefully considered a randomised control design. However it is not feasible as the effect of the intervention would make it obvious to participants whether or not they were receiving the blocker or a placebo. Additionally it is very unlikely to be acceptable to prospective participants to take part in a research design in which there is a chance they will not receive hormonal treatment. Further, as the numbers are small this would make it difficult to collect sufficient data. Additionally it is highly likely that those in the no treatment group would drop out of the study and seek private treatment.

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.

Young Person Information Sheet

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.

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:

- Look at 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?

You may be eligible for the study if:

- You have a diagnosis of Gender Identity Disorder. Some people describe this as feeling that you are in the wrong body or that your gender and body do not match.
- You are in early puberty. To check this, you 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 you more distressed and you want treatment to stop puberty developing further.
- Your parents/carer support your request for blocker treatment in early puberty.
- Your key workers at the Tavistock Centre have completed their assessment together with you and agree that you are eligible to enter the study.

Once the Tavistock assessment, physical examination and tests have been done, it can be decided whether you are eligible for the study. If you are not eligible 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 you are in early puberty, that you are physically fit for blocker treatment and that you 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 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. We will explain what each test involves beforehand.

Do I have to take part?

It is entirely up to you whether or not you want to take part. Even if you decide to enter 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 care you receive.

What will happen to me if I decide to take part?

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

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

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

After you finish the study at the age of 16, you will continue to see the Tavistock and UCLH gender identity teams and your 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, body shape or your final adult height.
2. Blocker treatment could affect your memory, concentration and mood.
3. Blocker treatment in early puberty could affect how you feel about your sex/gender and how likely you are to change your mind.
4. Blocker treatment could affect your fertility (your ability to have a baby). It could take 6 to 12 months or longer after stopping the blocker before boys start making sperm again or girls start maturing eggs in their ovaries.
5. There could be other long-term effects of blocker therapy in early puberty that we don't know about.

Will information about me be kept confidential?

If you decide to enter the study, we will let your GP know and tell them about the treatment you are being offered. We will also let your local Child and Adolescent Mental Health Service know if applicable. The information we collect about you during the study will be kept strictly confidential. We will not give your 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 you 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 4 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: +44 (0)20 8938 2130
Fax: +44 (0)20 7794 1879
Email: eskagerberg@tavi-port.nhs.uk

We have also given your parents/carer 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.