

Patient Information Sheet

Effects of testosterone levels on cardiovascular risk factors and well being in men with Type 2 diabetes

This is an observational study and there are no trial medications involved

10th October 2008

Part 1

You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take your time to decide whether or not you wish to take part.

Thank you for reading this.

What is the purpose of the study?

Testosterone (male hormone) treatment is usually given to men with low levels of testosterone to help with symptoms such as tiredness, weakness, moodiness, depression and loss of libido (sex drive). It also helps to maintain the strength of bones and reduce the risk of broken bones. The purpose of this study is to find out if testosterone levels are directly linked to cardiovascular diseases (heart disease) and its effect on obesity, diabetes and its complications, lipid levels (cholesterol and other fats). This will be a follow up after 4 – 8 years of our previous study which looked into testosterone levels in patients with diabetes. As you are likely to have been involved in that study we would like to invite you to take part in the follow up study. This study does not involve taking any new medications. It involves having a physical examination, as you have with any hospital consultations, taking blood and urine for further tests, filling in three questionnaires regarding your health and quality of life and an ultrasound scan of your blood vessels in the neck and groin (this is non invasive and does not involve radiation). You will have to come to the Diabetes centre on two occasions before breakfast and you will spend approximately one to two hours in the Diabetes centre.

Why have I been chosen?

You have been chosen for the study because you have Type 2 diabetes and you took part in the previous study a few years ago looking at the prevalence of hypogonadism (low testosterone levels) in Type 2 diabetes patients. We expect approximately 350 to 400 patients to take part in the study. All the patients will be recruited from Barnsley Hospital and the GP practices in and around the Barnsley area.

Do I have to take part?

No. It is up to you to decide whether or not to take part. If you do, you will be given this information sheet to keep and be asked to sign a consent form. You are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

What will happen if I take part?

If you agree to join the study we will ask you questions about your medical history and we will perform blood and urine tests. The study will involve two visits to Barnsley Hospital Diabetes Centre. You will need to be at the Diabetes centre for approximately two hours for one visit so that we can perform tests including blood and urine tests and ultrasound tests of the blood vessels in the neck and groin. The other visit will be much shorter because it will only involve blood tests. We will arrange these visits as early in the morning as possible - around 8 or 9am as blood tests should be done before you have eaten breakfast or taken your diabetes medication. On these days you should eat nothing and drink only water after 10 pm the night before. You will also do questionnaires on one of these visits.

During the study we will take blood for testing. Some of the blood will be used for a genetic DNA test to find out about your testosterone receptor if it is not already been tested before. We will ask you if you would consent to this test. This receptor is how testosterone acts in the body and may explain why some people get more effect from testosterone.

In the future we might have to do other blood tests on the blood we already have. Blood samples will be kept for future tests into diabetes, blood vessel disease or testosterone. In this sense your blood sample will be considered a gift to our research team. Blood tests and data from the trial will be kept securely in locked cabinets or freezers for seven years and then destroyed.

Comment [h1]: Might be better to say on the blood we already have or they may think they have to return.

Comment [h2]: This answers our information governance question, apart from how it will be destroyed.

During the trial you will make two visits to the Diabetes Centre and will need to pay for travel and parking on these occasions. We realise that you will need reimbursement of this money and will provide this when you finish the study.

Comment [h3]: Are we giving them a breakfast voucher or recompensing them at a later date?

Comment [h4]: Might we need receipts for this? Or are we paying a set fee?

What do I have to do?

During the trial you must agree to come to the Diabetes Centre for 2 visits as described above. It is important that you tell us at the beginning of the study which medicines you are taking including prescription medicines and those you have obtained yourself. We will not make any alterations to your medications including insulin.

What are the possible disadvantages and risks of taking part?

The blood samples we ask you to provide may cause some discomfort or bruising. You will have to spend approximately two hours in the Diabetes Centre for the study.

If you have private medical or life insurance you may wish to check with your insurers that being in the study does not affect the conditions of your policy.

What are the possible benefits of taking part?

Information from this study might help improve the treatment of people with diabetes or low testosterone levels in the future.

What happens when the research study stops?

After the study you will be informed about the major finding of the study and also in light of the tests if any modifications are needed for your treatment.

What happens if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. Detailed information on this is given in Part 2.

Will my taking part in the study be kept confidential?

Yes. All the information about your participation in this study will be kept confidential. The details are included in Part 2.

Contact for further information

You may ask questions about the study at any time. If you have any questions about the informed consent process or your rights as a research subject or require any additional information then you should contact us:

Dr V Muraleedharan
Centre for Diabetes and Endocrinology/ Research and Development
Barnsley Hospital NHS Foundation Trust
Gawber Road
Barnsley
S75 2EP
Telephone:
Dr V Muraleedharan - 01226 432147 or bleep 152 via switchboard (01226 730000)
Research Nurse Hazel Aldred on 01226 432520 or bleep 409 via switchboard.

This completes Part 1 of the Information Sheet. If the information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making any decision.

Part 2

What if new information becomes available?

Sometimes during the course of a study, new information becomes available about the condition that is being studied. If this happens, your research doctor might consider it to be in your best interests to withdraw you from the study. He will explain the reasons and arrange for your care to continue.

If the study is stopped for any reason, you will be told why and your continuing care will be arranged.

What will happen if I don't want to carry on with the study?

You can withdraw from the study at any time, without giving any reason, without my medical care be affected. Information and blood samples collected prior to your leaving the study may still be used.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your questions (01226 434532). If you have any further concerns, you can contact the Patient Advice and Liaison Service, John Armin, PALS Manager, Barnsley Hospital NHS Foundation Trust Gwaber Road Barnsley, S75 2EP Tel: 01226432430.

Comment [h5]: Again, wrong number.

In the event that something does go wrong and you are harmed during the research study there are no special compensation arrangements. If you are harmed and this is due to someone's negligence then you may have grounds for a legal action against Barnsley Hospital NHS Foundation Trust but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Will my taking part in this study be kept confidential?

All information relating to you, collected whilst on the study will be kept in strict medical confidence, it will be kept confidential and secure and will be used only for the purpose for which it was collected.

Comment [h6]: This is what I meant about returning to previous studies to recruit later.

It is a requirement that your involvement in this study is noted in your medical records and we will inform your family doctor and your hospital doctor, if you have one. Doctors and nurses working on the study will require direct access to your records. Members of the Research and Development department at Barnsley Hospital may also review your medical records to check that the trial has been properly carried out. By signing the consent form, you authorise access to this confidential information.

Data collected during this study will be reviewed, collected on a computer database and stored in electronic and manual files. Any data which could be linked to you will be stored in a locked draw in a locked room in Barnsley Hospital. Electronic data will be stored on the Barnsley Hospital computer system that is only open to authorised users and has appropriate security measures. Electronic data will not be linked to your name and will not be identifiable.

Comment [h7]: This answers our Info Governance also.

What will happen to any samples I give?

Blood and serum samples taken in the study will be stored for possible future research in to diabetes, testosterone or vascular disease. Samples will be stored securely in a room that is generally kept locked. Samples will have an identification number which is associated with you but will not be labelled with your name. Samples may be used by Professor Hugh Jones and his current or future research team. Samples will be kept for seven years and then destroyed.

Will any genetic tests be done?

A genetic test will determine the activity of the testosterone receptor. Testosterone links up with its receptor in order cause effects within the body. This receptor can vary genetically and this can lead to differences in the effect of testosterone. We will test if different receptor affects changes in diabetes with testosterone treatment. The genetic test will be done on a single blood sample. The individual results of the test are not meaningful at the moment but the results of the tests from all participants in the study will help us understand more about testosterone and diabetes. The test will not affect insurance premiums.

What will happen to the results of the research study?

At the end of the study the results will be detailed in a report and may be published in a medical journal or presented at a medical conference. You will not be identified in any of these. We will write to provide you with a summary of the results when the report is ready.

Who is organising and funding the research?

The research is organised by Professor Hugh Jones at the Centre of Diabetes and Endocrinology at Barnsley Hospital. The study is funded by the Endocrinology Research Fund at Barnsley Hospital and sponsored by Barnsley Hospital NHS Foundation Trust.

Thank you for reading this. If you decide to take part in the study you will be asked to sign a consent form. You will be given a copy of this information sheet and the signed consent form to keep. A copy of these forms will also be kept in your medical notes at Barnsley Hospital.

Who has reviewed the study?

The South Yorkshire Research Ethics Committee has reviewed and approved this study.