A study of TelmisArtan and InsuLin Resistance

Patient Information and Consent Form Version: 7.0 Date: 19/08/2014

www.tailortrial.org.uk

We would like to ask you to read this information about a research study. Then you may decide if you would be willing to take part. It is important for you to understand why the research is being done. This includes what it will involve and when. If you have any questions please ask the researchers or your clinical team.

1) Why is this study needed?

Patients treated with antiretroviral therapy can, and should, expect to have long and healthy lives. However, this patient group may be at a higher risk of developing diabetes and heart disease. There is evidence that this may occur at an earlier age than is seen normally.

This patient group may find changes in the way fat is stored in their body. There may be more fat around the stomach and liver. Fat may be lost from the face, arms and legs. These changes are thought to increase the risk of diabetes and heart disease.

Telmisartan is a medicine that is already used to reduce high blood pressure. It is also thought to be helpful in the prevention of heart disease.

We are researching whether telmisartan could be useful in:

a) Preventing diabetes
b) Preventing heart disease.
c) Reducing harmful changes in body fat

If this is so, we would also like to know what the best dose is. This medicine has been shown to reduce these risks in other patient groups. We are keen to find out if it may also benefit your patient group. All participants in the study will continue to receive their normal antiretroviral therapy.

Taking part in this study is voluntary. If you do take part then you will be asked to sign a consent form. You are still free to withdraw at any time and without giving a reason. This will not affect the care you receive.

2) Why have I been chosen?

Anyone that has taken antiretroviral therapy for at least 6 months may take part. We are recruiting 370 patients at different hospitals throughout the UK.

3) What will happen during the study?

We will try to arrange the study visits at the same time as your clinic visits.

Over a 12 month period there will be 4 study visits. The study visits will take about an hour. We will ask you to attend fasted (no food and drinking only water).

We will ask you to provide blood samples. This is so we can measure the level of glucose and insulin in your blood. We will check how your kidneys, liver, and heart are functioning with these blood samples. We will also ask you to provide a urine sample.

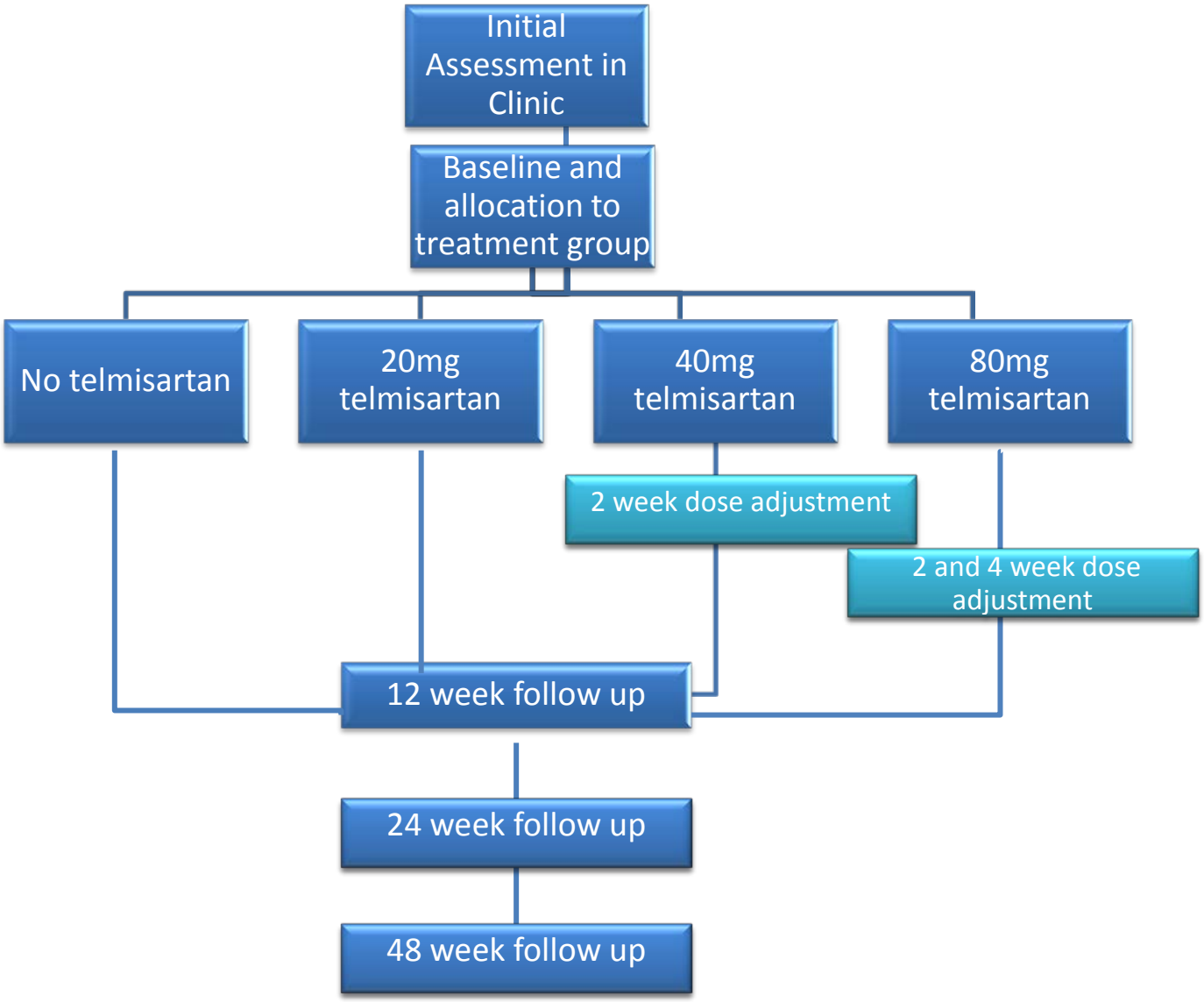
A physical examination may be performed. This will include measuring your blood pressure, height, weight etc. We will ask questions about your general health.

Some people will be asked to attend one or two more short visits. This will be to check their blood pressure and to change the medicine dose. There are no blood tests at these visits. You do not need to attend these visits fasting.

We would like to ask you if we might collect DNA from the blood sample. We know that some patients may respond to a medicine better than others. By collecting DNA, we may be able to find out if there is a genetic link. We understand that some patients prefer not to donate a DNA sample. You may still take part in the study even if you choose not to donate a DNA sample.

Treatment Allocation: We want to find out what is the best dose of this medicine. We will compare 4 groups of people. 3 groups will be given different doses of telmisartan. The other group will not be prescribed any telmisartan.

To ensure fairness, we use a computer program to allocate patients to each group. Please note that your personal details would not be put on the computer. You will have a 1 in 4 chance of being allocated to any group.



Telmisartan is a small tablet about this size  . It is smaller than a paracetamol tablet. It should be taken once a day, for up to 12 months. Each dose is usually available as one tablet.

Group 1: This group will be monitored. They will be asked to attend clinic visits for assessment as above. They will not be prescribed any telmisartan. We will compare them with the other groups.

Group 2: This group take one tablet of 20 mg telmisartan daily for 12 months.

Group 3: This group will start on 20 mg of telmisartan (one tablet daily). They will have an additional short clinic visit after 2 weeks. Their blood pressure will be checked and any side effects assessed. The dose will then be increased to 40 mg.

Group 4: This group will start on 20 mg telmisartan (one tablet daily). The dose will be increased after 2 weeks to 40 mg. After another 2 weeks the dose will be increased to 80 mg. They will remain on 80mg for the remainder of the study. This group will need two additional short clinic visits, 2 weeks apart. Their blood pressure and any side effects will be checked at these 2 visits.

We would like the patient to record in a diary when they take a tablet, as we need to know if the tablet is taken or not. We would also like to know any reason why the tablet has not been taken.

Travel expenses will be provided for attending additional visits to increase the dose of telmisartan.

The results will be looked at half-way through the study. If your dose is not effective, you will be asked to stop taking telmisartan. Your participation in the study will end at this point.

You will continue to receive your normal medication regardless of:

(a) Which group you are allocated; and

(b) Whether you stop participating in the study or continue in the study.

4) What if I am pregnant, plan to become pregnant or am breastfeeding?

Telmisartan is in a group of medicines that doctors should not prescribe during pregnancy. We would advise any women that may become pregnant use reliable contraception while in this study. Your doctor can advise you on how best to do this. You should not take part in this study if:

a) You are pregnant
b) Are planning to become pregnant in the next 12 months
c) Are breastfeeding.

After the telmisartan treatment stops there is no reason why you should not become pregnant. Women will be offered a pregnancy test before taking part and at each study visit.

If you become pregnant during the study, you should stop the telmisartan treatment. Please contact a member of the study team as soon as possible.

5) What are the side effects of telmisartan?

Many medicines have side effects but most are mild. However, we monitor this carefully during the study. Your doctor or nurse will fully explain the possible side effects of telmisartan to you. Should any side effects develop then you should stop taking the study medication.

You should discuss any side effects with your research team as soon as possible. They may advise you to stop treatment, continue, or reduce your dose.

Telmisartan is prescribed to treat high blood pressure. There is a possibility that some participants may experience low blood pressure. This may make you feel dizzy or faint. However, the risk of low blood pressure is rare. Blood pressure will be monitored before starting the study and at each visit. Anyone with lower than normal blood pressure will not take part in the study.

Telmisartan may cause a decrease in kidney function in some individuals. Mostly, those who already have kidney disease. Your kidney function will be checked during your routine clinic visits. If you have existing kidney disease, you will not take part in the study.

Possible side effects include nausea, vomiting and diarrhoea. In rare cases there may be serious side effects. For example, an allergic reaction, joint pains or flu-like illness. Some patients may experience a temporary change in taste sensation. We will also ask you about any side effects. As we will compare the benefit of taking the medication with any problems experienced.

6) What are the possible advantages and disadvantages of taking part?

If telmisartan is found to reduce risks it may become routinely prescribed. To find out if this medicine is effective we need to complete this research. We also need to complete this research to discover the best dose of the medication.

There is additional monitoring when participating in this research study. This may be associated with additional benefits to health.

If you are in a treatment group, you will take an additional tablet each day. The tablet is small and can be taken at any time of day. It can be taken at the same time as other medicines if you prefer. There is no effect on other medications that we are aware of.

You will need an extra clinic visit if you take part in the study. Where possible, study visits will be planned with your routine appointments.

7) What if there is a problem?

If you have a concern about this study, speak to the research team or your doctor. They will do their best to answer your questions. You may choose to stop participating in the study at any time. This will not affect your clinical care.

This study is sponsored by the NHS. As with all NHS care, there is a standard NHS Complaints Procedure. Details can be obtained from the hospital.

If you are harmed due to someone's negligence, you may have grounds for compensation. You can apply for compensation from the NHS Trust where you are treated. You may have to pay your legal costs. There are no additional compensation arrangements for the trial.

9) Will my taking part in this study be kept confidential?

Yes. People working on the study will have access to the data. The only other people are those that ensure the study is run correctly. All information collected about you during this study will be confidential. Data will be handled, stored and destroyed in accordance with the Data Protection Act 1998.

Your consent form will be sent to the Clinical Trials Unit at the University of Liverpool. It will be stored securely and confidentially. It will be stored separately to any other trial information.

You will be provided a letter to give to your GP should you wish to do so. You may also ask the research team to send this letter on your behalf.

10) What will happen to the biological samples I give?

All samples will have any personal details removed before sending to the University of Liverpool. Only the research team and monitors will have access to your personal data. This includes the Regulatory Authorities and Co-Sponsors who check the research is conducted properly.

You may choose to allow the researchers to collect DNA from your blood sample. This will not be traceable to you. It will be stored in a secure place and used in future studies. This may help us to identify people who would benefit most from the treatment.

Donating your DNA sample is optional. You can take part in the study even if you choose not to donate your DNA.

The research team are not receiving funding for any commercial reason for this study. Each individual sample will not be of any commercial value to the Universities and hospitals involved in the study. Any valuable discovery would arise from analysis of groups rather than single individuals.

11) What if new information becomes available?

The results will be looked at halfway through the study. Any doses of telmisartan found to be ineffective will stop at this point. If you are receiving one of these doses you will be asked to stop. If this happens, you will not need to attend further study visits. Your clinician will discuss any new information about telmisartan with you.

12) Do I have to take part, and can I change my mind?

Taking part is voluntary. You may withdraw from the study at any point. You do not have to give a reason. Withdrawal will not change the standard of care you receive now or in the future.

You may choose to withdraw from taking the medicine. In this case, we would ask if we may still collect data and/or blood samples.. If you decide to withdraw from the study completely, no

more information will be collected. Information collected up until the time of withdrawal will be included in the study analysis. You may request that this information be removed.

13) What happens to my treatment at the end of the study?

Once your participation in the study is ended, we are not able to prescribe Telmisartan. However, you will continue to receive your normal antiretroviral therapy.

If telmisartan proves to be effective, it may become part of standard care for your patient group

14) What will happen to the results of the study?

We aim to publish the results of this study in reputable medical literature. Your confidentiality will be ensured at all times. You will not be identified in any publication. A short summary of the study results be provided on our website (www.tailortrial.org.uk).

15) Who is running this study?

The study is funded by the Department of Health. It is being run by the doctors and nurses in your hospital. This study is organised by:

- Royal Liverpool and Broadgreen University Hospitals NHS Trust
- University of Liverpool
- University of Lancaster.

This research has been approved by a research ethics committee.

Please ask us if there is anything that is not clear or if you would like more information.

Please Contact:

Or Contact:

THANK YOU FOR READING THIS INFORMATION SHEET.
WE HOPE YOU HAVE FOUND THIS SHEET HELPFUL

A study of TelmisArtan and InsuLin Resistance

Consent Form Version: 7.0 Date: 19/08/2014

Centre Name: < > **Centre Code: <**

Name of Investigator: _____

Screening Number: |**S**|__|__|__|__|__|__|__|__|

Patient's date of birth |__|__|/|__|__|/|__|__|__|__|

	Please initial boxes
1. I confirm I have read and understand the information leaflet (version 7.0 dated 19/082014) for the above study, and have had the opportunity to ask questions and have these answered satisfactorily.	
2. I understand that my participation is voluntary and that I am free to withdraw from the study at any time without giving a reason and without my care or legal rights being affected.	
3. I understand that once my participation in the study is ended my treatment with telmisartan will also end.	
4. I understand that relevant sections of my medical notes and any data collected during the study may be looked at by authorised individuals from the research team, Regulatory Authorities, co-sponsors (Royal Liverpool and Broadgreen University Hospitals NHS Trust and University of Liverpool), or from the NHS trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records for this purpose.	
5. I understand that my medical data will be collected for this study and may be used to develop new research and that data protection regulations will be observed.	
6. I give permission for blood and urine samples to be taken, stored and used for this study and for future research and be transferred to research institutes in the UK.	
7. I agree to take part in the above study.	
8. I agree for my consent form and details, which will include my name and date of birth to be passed to the Clinical Trials Unit at the University of Liverpool for the administration of the study.	

OPTIONAL: I give permission for my DNA to be extracted, stored and used for future research and be transferred to research institutes in the UK.	Yes	No
OPTIONAL: I give permission for my GP to be informed via letter that I am taking part in this study	Yes	No

_____	_____	_____
Name of Participant	Signature	Date (dd-mm-yyyy)
	_____	_____
_____		
Researcher	Signature	Date (dd-mm-yyyy)

When completed, 1 (original) to be kept in medical notes, 1 for participant, 1 for researcher site file; 1 for the Coordinating Centre, University of Liverpool (fax on +44 (0) 151 706 5932)