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Body Fat Distribution Sub-Study (A study of TelmisArtan and InsuLin Resistance in HIV)

Patient Information and Consent Form (Sub-study) Version: 6.0 Date: 19/08/2014

www.tailortrial.org.uk

1) Why is this study needed?

Patients with HIV treated by combination antiretroviral therapy (cART) may develop abnormal changes in body fat distribution during the course of therapy. These changes include fat accumulation in the abdomen, fat loss from the face and limbs and importantly fat accumulation in the liver. Changes in the body fat distribution are known to increase the risk of reduced response to insulin (insulin resistance) leading to an increase in the risk of diabetes and cardiovascular disease. Telmisartan has been suggested to reduce harmful changes in body fat and thereby reduce insulin resistance. This sub-study will use magnetic resonance imaging (MRI) and magnetic resonance spectroscopy (MRS) to measure whether telmisartan can beneficially influence fat content in the whole body and in liver and leg muscle.

2) Why have I been chosen?

We would like to invite everyone taking HIV medication which may potentially cause insulin resistance to take part in this research study. You must have consented to take part in the main TAILoR study to take part in this sub-study. This sub-study will recruit 50 patients.

3) What will happen during the study?

You will be asked to undergo three separate MR scans – one MRI scan for your whole body and one MRS study each for your leg muscle and liver. These scans will take place when you come for your first clinic visit after agreeing to take part in the TAILoR study and then once more at your scheduled 6 month visit. The MR scans will be carried out in the Magnetic Resonance and Image Analysis Research Centre (MARIARC) at the University of Liverpool, or at another suitable local facility, and will add approximately 1 hour to your visit time.

The MRI scans will be conducted regardless of whichever treatment group you belong to.

You will not be paid for taking part in the study, however, if you have to attend clinic specifically to undergo the MRI scans we will pay you travel expenses to the value of £16 per MRI visit.

4) What precautions are to be undertaken before undergoing MRI or MRS?

You will be asked to fill in a safety screening form to make sure there are no reasons why you would not be suitable for MR scans. You will be asked to wear a gown (changing rooms are provided) and remove items which are affected by the magnetic field (e.g. hearing aids, mobile phones, keys, coins, pens, credit cards (secure lockers are provided). MR scans are noisy so you will need to wear the ear protection that will be provided. MR scans cause no pain, harm or long-term effects. Some people may experience slight feeling of claustrophobia in the scanner. If you do feel uncomfortable you will be able to notify us immediately and we will take you out of the scanner without delay.

5) What are the side effects of undergoing MRI or MRS?

There are no known risks in properly conducted magnetic resonance scanning. As it involves a strong magnetic field, certain standard precautions will be observed. Most importantly, we will NOT study you if you are fitted with a heart pacemaker, mini-defibrillator or a neurostimulator; if you have surgical clips in your head; if you have suffered injuries which may have left metal particles in your eye or head, or elsewhere in your body; or if you have an artificial heart valve. We will also ask about other kinds of surgery and metal implant which might affect your suitability. Some people find the scanner a claustrophobic or uncomfortable environment, and we will ask you about this.

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

The study will cause you a little added inconvenience because you will need to go to a facility close to your clinic to have the MRI study. This will also add travel time and the scan will take approximately 1 hour..

Occasionally research studies using magnetic resonance imaging reveal significant unexpected abnormalities which require medical follow-up, either for further investigation or (more rarely) treatment. The scans we do are for research purposes, and generally are not useful in diagnosing disease or other abnormality. However, they will be reviewed carefully for obvious and significant abnormality. If any unexpected abnormalities that are medically significant are found, we will write to your HIV doctor after obtaining consent from you; your HIV doctor will then be able to take it further with you. Please note that this is not a substitute for a 'medical' magnetic resonance scan that a doctor might order to make a diagnosis. It should therefore not be seen as a 'health check'.

7) What are the possible benefits of taking part?

The information we get from this study may help us to identify whether telmisartan causes any beneficial changes in body fat distribution and therefore help in improving future treatments for HIV patients and reduce HIV treatment-related side effects.

8) What if there is a problem?

Please see answer to Q 8 in the Patient Information Sheet for the main study.

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

Yes. Please see answer to Q 9 in the Patient Information Sheet for the main study.

10) What will happen to my MRI/MRS data?

Part of the data obtained from the MR scans will be anonymised and securely transferred to Vardis Group, London to perform data analysis; the other part will be accessed for analysis only by those who are part of the study research team. If your MRI/MRS data show any unexpected abnormalities that are medically significant, this will be communicated to your HIV doctor after obtaining consent from you. Your HIV doctor will then be able to take it further with you.

11) What if new information becomes available?

Please see answer to Q 11 in the Patient Information Sheet for the main study.

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

Please see answer to Q 12 in the Patient Information Sheet for the main study. In addition to this, if you wish, you may withdraw from the sub study but remain in the main study. Any such decision will not affect your standard of care in any way.

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

Please see answer to Q 13 in the Patient Information Sheet for the main study.

14) Who is doing this study?

Please see answer to Q 14 in the Patient Information Sheet for the main study.

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

Please Contact:	< Insert Name and Title>
	<Telephone Number>
Or Contact:	< Insert Name and Title>
	<Telephone Number>

THANK YOU FOR READING THIS INFORMATION SHEET.

<Hospital logo>
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WE HOPE YOU HAVE FOUND THIS SHEET HELPFUL

Body Fat Distribution Sub-Study (A study of TelmisArtan and InsuLin Resistance in HIV)

Consent Form (Sub-study) Version: 6.0 Date:

19/08/2014

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

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 6.0 dated 19/08/2014) 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 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. ☐

4. I understand that some parts of the data collected during the study may be sent anonymised to Vardis Group, London to undertake data analysis. I give permission for them to have access to my anonymised data for this purpose. ☐

5. I give permission for undergoing whole body MRI and leg and liver MRS and the resultant data to be stored and used for this study and for future research in HIV. ☐

6. I understand that any medically significant coincidental findings revealed during the MRI and MRS will be reported to my HIV clinical team for follow-up. I give permission for this information to be communicated to my HIV clinical team. ☐

7. I agree for my consent form and details, which will include my name and date of birth to be passed to the University of Liverpool for the administration of the study. ☐

8. I agree to take part in the above study. ☐

_____	_____	_____
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) 151706 5932)