NUTRITIONAL SUPPORT FOR AFRICAN ADULTS STARTING ANTIRETROVIRAL THERAPY (NUSTART)

Information sheet ***(****to be kept by participant)*

We have invited you to participate in a trial which is designed to see if we can improve health and survival in patients who are just about to start taking antiretroviral medication against HIV. Previous studies in Zambia and elsewhere have shown that nutrition problems have a big impact on the health of people with HIV infection. In this trial we want to find out if a nutritional supplement with high dose vitamins and minerals is better than the normal supplement made out of groundnuts.

If you are willing to participate in this study we are going to give you a food supplement made of groundnut paste in a foil packet. This will be in two stages: first in small quantities and then large quantities as you begin to put on weight. You may be given a supplement with high dose vitamins and minerals, or you may receive a regular supplement. No one is going to decide which supplement to give you nor will the staff know which supplement you are receiving: the packets of supplement have already been prepared in France using a computer code so that no one knows what each packet contains. This is important so that we make unbiased assessments of your progress.

What are we asking you to do?

You will continue to be cared for at your local clinic and will be given your antiretroviral drugs from there. Besides the local ART clinic visits we will require you to come for 3 extra visits and two of these visits will be to UTH. We will provide transport. When you come to UTH we will take detailed body measurements which take 4 to 5 hours. These measurements include sitting in a "Bodpod" capsule for less than a minute, and the "deuterium dilution" test which involves giving some small amount of saliva. We will show you photographs of what these look like. All these tests are completely painless. When you are seen at the local clinic the visit will be for 30 to 60 minutes, including a simple test to measure your appetite by observing how much porridge you eat. During the study we will collect 6 extra samples of blood; most of these will be 7mls (one and half tea spoons) but on two occasions the amount collected will be 20mls (4 teaspoons).

What do we do with the samples we take?

The samples we will collect from you will be used initially for the HIV test and for the CD4 count (which is a measure of how HIV is affecting the immune system). Most of the blood samples are required for monitoring the amount of potassium and phosphate in the blood which is simply good practice when giving these minerals, and to ensure safety. The two samples which involve collecting larger volumes of blood will be used to assess changes in iron in the body and

to analyse immune cells in a bit more detail. Part of every blood sample will be stored in a big freezer so that we can measure vitamins and minerals and immune cells at a later date. During storage, samples are identifiable with a code so that no-one can see whose samples are being held without referring to our highly confidential register.

What are the possible benefits to me?

If you agree to participate in any part of this study, you will be monitored medically more closely than is otherwise possible, including the opportunity to visit the study team if you feel unwell or if you just need to ask questions or discuss things, and you will receive a nutritional supplement.

What are the possible disadvantages to me?

The main disadvantage is the blood sampling which will be done at every visit. Although the blood sampling is frequent, the total volume is 68ml, which will not affect your health to any measurable degree. The other disadvantage is the inconvenience of spending two half-days in UTH for the detailed measurements. The nutritional supplement is very safe and has been designed by a team of international experts specifically for this trial, but if something did go wrong, compensation will be available from an insurance company which has provided insurance for medical accidents.

Confidentiality

Your details will be recorded on a paper form which will be locked away in our offices in UTH. Your details will be entered on a computer but only in coded form and your name will not be included, only your enrolment number, and only this number will be used to label any stored samples. Any information and results obtained will remain absolutely confidential, and other family members or work colleagues will not be granted access to this information.

The study is voluntary

You do not have to participate in this study if you do not want to, and even if you refuse to participate in the study, we will still provide the best care we can. If you do agree, you are also free to change your mind at a later date. This research study has been approved by the Research Ethics Committee of the University of Zambia and their contact details are given below.

Contact details of Principal Investigator: Dr Lackson Kasonka, Department of Obstetrics & Gynaecology, University Teaching Hospital, Nationalist Rd, Lusaka (phone 0211 252269).

Contact details of Research Ethics Committee: The Chairperson, REC office, Department of Anatomy, Ridgeway Campus, Nationalist Rd, Lusaka (phone 0211 256067).

NUTRITIONAL SUPPORT FOR AFRICAN ADULTS STARTING ANTIRETROVIRAL THERAPY (NUSTART)

Consent record sheet *(to be kept by study team)*

I confirm that I have understood the information I have been given about the study. I agree to participate in the study. I confirm that I am joining the study of my free will and that I can withdraw at any time without affecting the care available to me. I understand what will be required of me.

Name

Signed (or thumbprint)

Date

Signature (or thumbprint) of witness

Name

Date

I confirm that I have explained the information fully and answered any questions.

Signed for the study team

Name

Date