InvesTigation and Analysis of uRine – Glucose control in patiEnts with Type 2 diabetes – **TARGET** study

Participant Information Sheet

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Professor of Primary Care Diabetes & Vascular Medicine

Researcher Introduction

My name is Hanad Osman and I am a PhD student at the University of Leicester. I would like to invite you to take part in a research study I am completing as part of my PhD qualification.

Introduction

You are being invited to take part in a research study. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read this information sheet carefully and discuss with others if you wish. It is up to you to decide whether or not to take part. If you decide to take part, you are still free to change your mind at any time during the study. That decision will not affect the care you receive in anyway.

If there is any part of this information sheet that you do not understand, or require further information about, please contact us and we will be happy to answer any questions you have. Our contact details are on the back page.

What is the purpose of the research project?

This study seeks to compare the different methods used to assess how well people take their medications. Commonly used methods currently used to assess how people take their medications include short questionnaires directly asking people how well they take their medications and also looking at medication records which can provide an indication of how regularly people are requesting their medications from their GP.

This study will be comparing the above mentioned methods with a chemical test that can establish whether medications are present in people's urine and/or blood samples.

This study will provide valuable information on the management of people diagnosed with type 2 diabetes.

Why have I been invited to participate?

You have been asked to participate as you have been categorised as having uncontrolled type 2 diabetes and are taking at least one oral medication for diabetes and one other medication for high blood pressure and/or high cholesterol.

Do I have to take part?

No, taking part in this study is voluntary. If you do not wish to take part, this will not affect any ongoing care that you receive. If you do decide to take part but later change your mind, you are free to withdraw at any time by contacting the research team using the information provided at the end of this document. If you do decide to take part, you will be asked to sign a consent form and you will be given a copy for your records.

What will happen to me if I take part?

If you agree to take part after reading this information sheet, a member of the research team will approach you during your visit to the GP practice. You will be taken to a private consultation room where you will be able to ask questions of them. You may also be asked questions about your medical history. These questions may include asking about whether you are pregnant or planning to become pregnant or whether you have been diagnosed with a major medical condition or terminal illness. These questions will be asked of all potential participants to ensure that you can take part in the study.

You will also be asked to complete a short questionnaire about how you take your medications. We do not expect this to take longer than 5 minutes.

We will then request you to provide us a with a blood sample of around 20mls (2 tablespoons) and a urine sample (around 5-10mls). These samples will be collected from you at your GP practice by your usual healthcare team. The samples will be analysed to detect the presence of certain medications that you take for type 2 diabetes and other related conditions. This will be the end of your participation in the study. We anticipate it will not take more than 30-45 minutes of your time.

We will also view your records with your surgery to look at previous history of medicines and illnesses.

If you agree to participate in the study, your GP will be informed of your participation.

What will happen to any samples that I provide during and after the research?

Blood and urine samples will be stored in a secure area with restricted access in an NHS facility. Only the Principal Investigator or a designated member of the research team will have access to the samples.

At the end of the study, with your permission, we would like to keep your remaining blood and urine samples for use in future ethically approved research.

For this type of study, we will store the anonymous research data and any research documents with personal information, such as consent forms, securely at the University of Leicester for 6 years. If you give us permission to retain your samples for future research, it is necessary to retain your

consent form until the samples have been depleted or destroyed, or if you withdraw your permission. This may be longer than 6 years.

The Human Tissue Authority is the regulatory authority responsible for the oversight and Inspections of human tissue storage in the UK after a study has concluded. We require your consent form to comply with the Human Tissue Authority to ensure we have obtained your permission to retain the samples beyond the life of this project. Your consent form would be stored independently from your pseudonymised samples to ensure your samples remain anonymous to researchers that may use them in the future.

If your samples are used up within this period, your consent form and personal information will be destroyed at the end of 6 years.

What are the possible benefits of taking part?

There will be no direct benefits for you taking part however the information we obtain from this study may help improve the treatment of people who have been diagnosed with type 2 diabetes. Also people at risk of complications from type 2 diabetes may be able to be assessed, diagnosed and treated more appropriately. Your participation is highly valued.

What are the possible disadvantages and risks of taking part?

Blood and urine samples are normally taken as part of your routine treatment and care and therefore we do not foresee any additional risks of taking part. You may however need to spend more time than you usually would at the GP surgery.

What if something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak with a member of the study team who will do their best to answer your questions. If you have concerns about any aspect of the way you have been approached or treated during the course of the study, you may wish to contact the hospital's Patient Information and Liaison Service (PILS). Contact details for the research team and PILS office can be found below. If you remain unhappy and wish to complain formally, you can do this through the NHS complaints procedure. Details can be obtained from the PILS office or from the hospital.

It is very unlikely that you would be harmed by taking part in this type of research study. In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against University of Leicester but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

If you wish to make a complaint, or require advice about taking part in the study you can contact:

Patient Information & Liaison Service at pils.complaints.compliments@uhl-tr.nhs.uk. The Firs, c/o Glenfield Hospital, Groby Road, Leicester. LE3 9QP

Freephone: 0808 1788337

Will my participation be kept confidential?

On the consent form, you can also choose to be informed about the results of the trial. If you consent for this to happen, we will store your contact details securely, separately from your survey form and clinical information, and we will only use them for the purposes you have chosen. Your contact details will be destroyed once they have been used for the purpose that you have agreed to.

We take confidentiality very seriously. As we will be using information from you in order to undertake this study, the University of Leicester will act as the data controller for this study. This means that we are responsible for looking after your information, keeping it confidential and using it properly. The study is taking place for 2 years. Anonymised research data will be stored for 6 years after the study has finished.

Your data may be accessed by authorised individuals from the Sponsor (University of Leicester), regulatory authorities, and the host NHS organisation, for monitoring and audit purposes. We have a duty of confidentiality to you as a research participant.

You should be aware that we have a professional and ethical duty to act on concerns for your safety and welfare. If we identify welfare issues, such as deteriorating illness or concerns of abuse, we may need to report these to your GP, your hospital team, or social services. We will tell you if we do this.

How will we use information about you?

We will need to use information from your medical records for this research project.

This information will include your:

- Initials
- Name
- Age
- Contact details
- List of medications

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

Where can you find out more about how your information is used?

- at www.hra.nhs.uk/information-about-patients/
- on the following website: www.le.ac.uk/patient-gdpr-guidance
- by asking one of the research team
- by contacting us via the e-mail address or phone number at the end of this sheet
- by contacting the University's Data Protection Officer, Parmjit Gill, University of Leicester, University Road, Leicester, LE1 7RH. Please email ias@le.ac.uk, or ring 0116 229 794.

What will happen to the results of the research project?

Once we have analysed the results, we will present the findings in a PhD thesis, at scientific meetings, across Leicester Diabetes Centre networks for educational purposes, and in medical research journals. All these results will be anonymous, and it would not be possible to identify you.

What should I do if I want to take part?

You will be asked to complete an Informed Consent Form and to opt-in to a variety of research options by placing your initials within the Yes or No box. This will confirm you understand how your data will be processed, protected and reviewed for research purposes.

Who is organising and funding the research project?

The data collected during this study forms part of a PhD project. The study is being run by investigators based at the Leicester Diabetes Centre which is part of the Department of Health Sciences at the University of Leicester and University Hospitals of Leicester NHS Trust. This study is being sponsored by the University of Leicester. All student activity is being supervised by senior researchers within Leicester Diabetes Centre and University Hospitals of Leicester NHS Trust.

This study has been funded by Servier as an unrestricted grant. Servier is an international pharmaceutical company governed by a non-profit foundation.

Servier derives no direct commercial benefit from the grant, and they will have no access to any personal information of the individual participants of the study. The study has been designed without any input, direct or otherwise, from Servier.

Who has reviewed the research project?

All research that involves NHS patients or staff, information from NHS medical records or uses NHS premises or facilities must be approved by an NHS Research Ethics Committee before it goes ahead. This research was approved by the Brighton & Sussex Research Ethics Committee. Approval means that the committee is satisfied that your rights will be respected, that any risks have been reduced to a minimum and balanced against possible benefits and that you have been given sufficient information on which to make an informed decision.

The study has also been reviewed by the University of Leicester.

Thank you for taking the time to read this information and consider taking part in this research

Contact for Further Information

If you require any further information, you can contact the following:

Hanad Osman
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Leicester Diabetes Centre
Leicester General Hospital
Gwendolen Road, Leicester, LE5 4PW
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