Patient Information Sheet

Full Study title: A Randomised Controlled International Multicentre Study evaluating changes in Metabolic Syndrome in Smokers with type 2 Diabetes Mellitus after switching from Tobacco Cigarettes to Combustion-Free Nicotine Delivery Systems: DIASMOKE Study.

Study Acronym: DIASMOKE

Short Study Title: Metabolic Syndrome in Diabetic Smokers using Cigarettes & Combustion-Free Nicotine Delivery Systems

***Dear Patient**,*

We would like to ask you to take part in our clinical investigation study. Before you decide whether you would like to take part it is important that you understand why this research is being done and what it will involve. One of our team will go through this information sheet with you and answer any questions or concerns you may have. Please ask us if there is anything that is not clear or if you would like more information and talk to others if you wish. You may take as much time as you wish before you decide whether you would like to take part in this study.

This information sheet will explain the purpose of the study and what will happen to you if you take part.

Thank you for taking the time to read this document.

What is the purpose of the study?

This study investigates whether vaping or using E-cigarettes reduces the risk of cardiovascular (heart and circulation) disease as compared to normal smoking. The results of the study may help us to understand more about the risks of vaping or e-cigarettes and normal cigarettes for diabetes patients who are smokers.

Why have I been chosen?

You will be invited to participate in this study if you are smoker and have diabetes and you have certain characteristics that have been set for the study.

Do I have to take part?

Your participation in this study is completely voluntary. You do not have to take part and you do not have to make your decision immediately. Please take the time to read this information sheet carefully and discuss it with relatives, friends and your GP if you wish.

It is up to you to decide whether or not to take part in this study. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. You will be 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.

If you have any questions or concerns about this study, or if you do not fully understand any part of it, please ask the researchers (there are contact details at the end of this sheet).

What will happen if I take part?

If you are interested in taking part in this study, we will make sure that you understand the purpose of the study, and what taking part involves for you; also to answer any questions that you have. If you are happy to go ahead you will be invited to a baseline check around one month after your initial discussion about the study, and we will ask you to sign a consent form.

The study will last for around 2 years in total. After your baseline check, you will be asked to come back for four further checks after 3 months, 6 months, one year and two years.

Everyone who joins the study will be randomly chosen to be in one of two groups of participants. One group will be asked to carry on smoking their usual cigarettes for the duration of the study, and the second group will be asked to switch to vaping or using E-cigarettes (technically known as a 'non-combustible nicotine delivery system') instead of normal cigarettes. You will be asked to keep to the method chosen for the group you are in for as long as you are in the study.

At your baseline check we will take a 'fasting blood sample' so you will be asked not to eat or drink anything overnight before the appointment. We will also ask you to refrain from drinking alcohol for 24 hours before your appointment. During the visit we will ask some details about your medical history and your smoking, take some measurements and give you a short questionnaire. Please note that you will also be advised not to consume on average more than 14 units of alcohol per week for the duration of the study.

Finally, we will install the Diasmoke App on to your personal device. We will ask you to complete a daily health questionnaire to track some aspects of your lifestyle between each visit. The questionnaire will take approximately 1 minute to complete each day and will allow for us to have daily insight into how you are getting on with the trial.

If you are in the group using vaping or E-cigarettes, we will show you different devices you can use, so that you can chose what works best for you. We will explain how to use them, and provide you with tobacco sticks or e-liquids appropriate for your device throughout the study.

At the later visits (at 3 months, 6 months, one year and two years), you will be given a morning appointment, and asked to fast overnight before the visit and again refrain from drinking alcohol 24 hour before the visit. You will have a similar set of questions, tests and measurements to the baseline check. If you are in the group using vaping/E-cigarettes we will ask about how you have been getting on with these.

What types of test or analysis will be carried out on the samples and what will happen to any samples I give?

The study will include collection of Blood samples and Urine Samples from you.

Blood samples will measure: CBC (WBC Hb, platelets), lipid profile (Triglycerides, LDL and HDL cholesterol) HbA1C, Insulin level, Testosterone (men only) and, Urine samples will measure Urine Albumin Creatinine Ratio.

Only the Direct Clinical & Research Team at the NHS Trust will collect these samples.

All samples will be stored in a secure facility in an anonymised form at St Peters Hospital and sent to the Pathology department for analysis. Only the research team will have access to the samples.

If you withdraw your consent from participating further in the study after samples have been taken from you, your samples will be destroyed in accordance with the Human Tissue Authority's Code of Practice and no new data will be generated from your samples. However, existing data cannot be removed.

Will expenses be paid?

If you have to make a special trip to the hospital as a result of taking part of this study, when you do not have a routine hospital appointment, we will be able to reimburse your travel expenses.

What are the possible benefits of taking part?

There may be no direct benefit to you from the study, apart from closer monitoring and medical supervision than would usually be available through standard NHS care. **All participants can stop using cigarettes at any point in the study and this is the preferred option from a health point of view.** However, your participation will be important as it will help us understand more about the effects of smoking and vaping or E-cigarettes, and this may help us to improve recommendations and treatments for people with diabetes in the future.

If you are chosen to be in the group trying vaping or E-cigarettes you will have a chance to try a different product instead of cigarettes.

What are the possible disadvantages and risks of taking part?

This will depend on which group you are allocated to in the study. If you are chosen to continue with your usual cigarettes, there will be no additional risks or disadvantages to taking part in the study. However, risks posed by smoking such as respiratory/cardiovascular will continue to increase with time. If you are chosen to try vaping or E-cigarettes, it is possible that you might have a reaction to the products. We will be monitoring this very carefully, and will ensure that if you have any problems they will be dealt with immediately. If necessary, you would be withdrawn from the study. You will have access to trial physician on priority basis to deal with any risk or adverse event.

We do not expect there to be any risks from the tests and assessments we will be carrying out, and trained staff will be supervising you at all times. If you have any problems they will be able to stop the test if necessary.

Whichever group you are allocated to, your normal care and treatment will continue unaffected.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this by contacting our hospital. Should you require advice in making your complaint, officers from the [*Insert local hospital details*] Patient Advice and Liaison Service (PALS) at St Peter's Hospital will be able to help you. Their contact details are:

Telephone: 01932 723553
Email: Asp-tr.patient.advice@nhs.net

What if something goes wrong? What arrangements are in place to cover me in terms of compensation?

Indemnification for non-negligent harm will be provided by the sponsor in full accordance with the Association of the British Pharmaceutical Industry (ABPI) guidance. The sponsor company holds an insurance policy providing Primary No Fault Compensation Clinical Trials Insurance to compensate you from any harm arising due to the design and management of this research. The NHS indemnity is also in place which will cover you in case any harm arises during the conduct of this research.

What will happen if I forget to use the app?

If you consent to the study protocol, you will be agreeing to have the Diasmoke App uploaded onto your device. Of course, we do not expect 100% compliance with the app. However, poor compliance (less than 70%) will likely be discussed within the trial team. We will send you gentle reminders to complete the daily data before the decision is made to potentially withdrawal from the study.

What will happen if I decide to withdraw at any point?

You are free to withdraw your participation at any time without any effect on your standard of care. We will need to use the data collected on you up until the time of your withdrawal.

Will my taking part in this study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence.

How will we use information about you?

We will need to use information from you and from your medical records for this research project. This information will include your name, contact details and NHS number. 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.

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

You can find out more about how we use your information:

- At www.hra.nhs.uk/information-about-patients/
- our leaflet available from the research team
- by asking one of the research team
- by sending an email to: asp-tr.rd-research-and-development@nhs.net

How long will my personal data be stored or accessed after the study has ended?

Your persona data will be stored or accessed for 6-12 months after the study has ended. Your identifiable details will be coded. Data will be stored in the Trust under lock and key. The computers will be password protected as per Trust policies. The Trust Confidentiality Policies, GCP guidelines, Data Protection Act 2018 and General Data Protection Regulations (GDPR) will be strictly followed at all times to ensure the confidentiality of your personal data.
Only the Chief Investigator, Principal Investigator and research team will have access to your personal data during the study. The research team is part of clinical care team.

What will happen to the results of the research study?

After the end of this study the results will be analysed and published in medical scientific journals. All the information you provide will be combined with the results from everyone else and it will not be possible to identify any individual from the results. It will take time for all the patients to finish this clinical study, so publication of the overall results will probably not be

possible for some time. If you are interested in reading the publication of the results, please feel free to ask the research team for any information. Results will also be updated on the hospitals research and development website, which is located at:

http://www.ashfordstpeters.nhs.uk/about-us/research-and-development

Who is organising and funding the study?

This study has been organised and is sponsored by ECLAT Limited, a spin off company of the University of Catania in Italy. They will reimburse St Peter's Hospital for research team's time including you in this study.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the London - Hampstead Research Ethics Committee, REC Reference number 20/LO/0704.

Contact for Further Information

Please feel free to ask any question you have about this study. If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions.

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