EndoBarrier TM Gastrointestinal Liner Diabetes Trial

SUMMARY OF RESEARCH STUDY

Study Project Title: EndoBarrier TM Gastrointestinal Liner Diabetes Trial

You are being invited to take part in a research study taking place at Imperial College London, St Mary's Hospital . The study investigates the effect of a new non-surgical device (EndoBarrier) on type 2 diabetes mellitus and weight loss over a period of 2 years. If after reading this you would like more information about the EndoBarrier trial, please complete the attached questionnaire and return in the envelope provided.

What is the purpose of the study?

A new device called the EndoBarrier Gastrointestinal Liner helps patients with diabetes manage their blood sugar levels and lose weight without the need for surgery. This study will compare how effective the EndoBarrier device is compared to standard medical care in the treatment of type 2 diabetes mellitus.

Why have I been invited?

You are being invited because your body mass index (BMI) is between 30-50 kg/ m^2 and you have type 2 diabetes mellitus.

How does EndoBarrier work?

The EndoBarrier has been shown to help control type 2 diabetes mellitus and reduce weight. It is a 60 cm long impermeable sleeve-like device that is inserted through your stomach (endoscopically) and creates a thin plastic layer between food and the wall of the intestine. This could prevent food from coming into contact with the gut until further down the intestine and may alter natural your level of hunger and fullness.

What will happen to me if I take part?

If you are interested in this study we will invite you for a screening visit. If you decide to participate you will be asked to sign an informed consent form. Your doctor will then perform some tests and procedures to determine whether you are eligible for the study.

If you are eligible for the study you will be randomised to either receive the EndoBarrier device for 12 months and subsequently a diet for a further 12 months after the implant, or you will receive a standard medical therapy and a diet for 24 months. All patients will receive specialist support from a doctor specialising in the treatment of diabetes and a dietitian.
Randomisation means that a group of people are split into two groups at random; one group is given one intervention (the EndoBarrier device) and the other is given a different intervention (standard medical therapy/ control group). We then measure how each group is doing and see if one group has achieved its supposed outcome any better.

On your second study visit we will inform you about the treatment for which you have been randomised for the duration of the study. We will further inform you about other tests performed while being on this trial. Your dietitian will assess your diet and give you specific dietary information.

On some of the study visits, we will also ask you to participate in specific tests which will help us to assess your metabolism, brain activity, insulin sensitivity and food preference. Participation in these tests is entirely optional. More information about these tests can be found in the patient information sheet.

On visit 4 you will either have the EndoBarrier device inserted (EndoBarrier group) or you will see the diabetic specialist doctor or nurse (Medical Therapy group). You will also see the dietitian for review.

During some study visits, you will see the diabetic specialist doctor or nurse, the gastroenterologist (EndoBarrier group only), and the dietitian for review.

If you are in the EndoBarrier group, your EndoBarrier will be removed after 12 months.

What happens if I want to withdraw from the study?

There are no foreseeable reasons why you should end your participation but you may withdraw from the study at any time.

What are the possible advantages and disadvantages of taking part?

Your direct benefit of taking part in this research will be the possible improvement in your blood glucose and HbA1c, blood pressure, weight loss and reduction in long term health risks particularly cardiovascular diseases.

The risks associated with the EndoBarrier procedure include the same risks observed with other upper gastrointestinal endoscopic procedures.

If you are randomised into the EndoBarrier group of the study, the frequent side effects are: cramps/abdominal pain, nausea/vomiting and/ or bloating. Other rare side effects are described in the Participant Information Sheet. If you are randomised into the control arm of the study, no side-effects are expected. More information of potential benefits and risks are outlined in the Participant Information Sheet.

What are the payments for this study?

On each visit, you will be reimbursed for your travel to the hospital.

Contact Information

Dr Prechtl or Dr Mohanaruban can be contacted on 07872850052 or 02075945946. The research nurse can be contacted on 020 331 25745.

Thank you for taking the time to read and consider this information sheet.

<u>Please complete this reply slip and return in the envelope provided</u> to the research centre. This will let the research team know if you would like more information about the EndoBarrier study.

Name	
Address	
Telephone	
Mobile	
E mail	
I am interested in finding out more about the EndoBarrier research project. I am happy for a member of the research team to contact me.	☐
I give permission for the Research Team to contact my GP to check whether there is any medical reason why I should not take part, and to confirm my medical history.	☐
SIGN :	
DATE :	

To speak to the research team about the EndoBarrier study, please contact:

Christwishes Makahamadze via post: Imperial College NHS Trust, St Mary's Hospital First Floor, Mint Wing, Office 3, Praed Street, Paddington, London, W2 1NY, or via email: endobarrier@imperial.nhs.uk or via Telephone: 020 331 25745, Mobile: 078 7285 0052.