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Patient Information Sheet

Project Title: A PILOT STUDY TO ASSESS THE DIAGNOSTIC UTILITY OF LUMBAR FACET MEDIAL BRANCH BLOCKS FOR IDENTIFYING RESPONDERS TO STIMULATION OF THE MEDIAL BRANCH OF THE DORSAL RAMUS IN CHRONIC LOW BACK PAIN PATIENTS

Dear Patient,

We would like to ask if you are willing to participate in the research study described below. This form explains why this research study is being done and what your role will be if you decide to participate. This form also describes the possible benefits/risks that may happen if you take part in this study.

Please read this information carefully, and ask your study doctor any questions you may have about the research study; so that your questions may be answered before you decide if you want to take part in the study. Please take your time and talk about this information with your family, friends, or family doctor.

Your participation in this study is voluntary. Therefore, you will only be enrolled to participate in the study if you consent to this in writing.

1. Why is this study being conducted?

Low back pain can have debilitating effects on patients and their support networks. Guidelines which recommend combined physiological, psychological and medication treatment do not always work for everyone. This results in patients experiencing little relief from their pain which places high demands on healthcare services.

Previous research has shown that a device, called the ReActiv8, can help with relieving pain in patients who have low back pain. Like most treatments, some patients respond more readily or over a different time course than others. However, it is currently not known how to identify patients who are likely to experience high levels of pain relief with this device.

In this study, we are collecting information to try to understand who receives the most benefit from the ReActiv8 device. By understanding how you respond to injections in your back, we hope to learn how to predict the amount and timing of benefit other patients will receive when they are treated with the ReActiv8 device.

ReActiv8 is a registered CE marked medical device in the UK; and covered by the NHS.

The study sponsor is Leeds Teaching Hospitals NHS Trust and funding for this research study was provided by Mainstay Medical Limited.

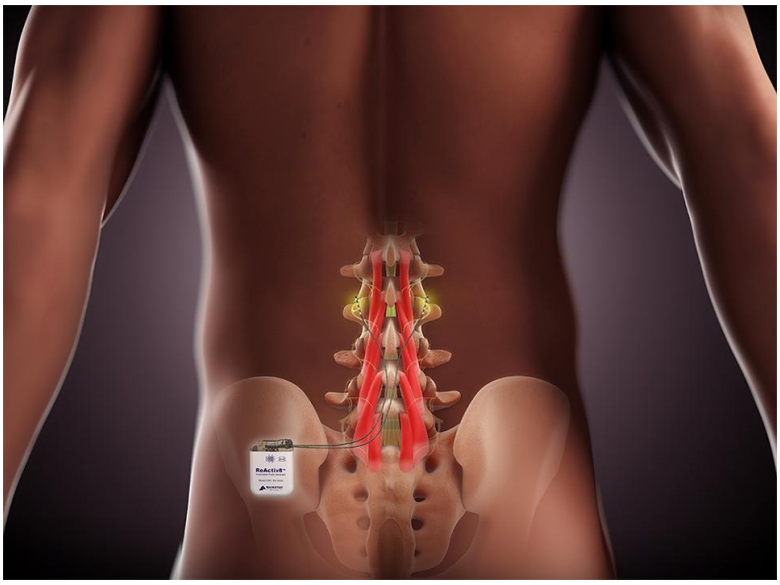
2. What is ReActiv8?

ReActiv8 is an approved CE marked medical device in the UK, Europe, USA and Australia that is intended for the treatment of chronic low back pain.

ReActiv8 therapy may be considered as an option if the following describes your situation

- You have had back pain for more than 3 months and it is affecting your ability to function.
- You have completed an expert guided exercise program and continue to be impaired by low back pain.
- You are motivated to explore a new option.
- Your doctor says that this is the right option for your kind of pain.

ReActiv8 is a neurostimulator that directly activates a specific nerve, the medial branch of the dorsal ramus. This nerve has several functions that include transmitting motor and sensory information between the Multifidus muscle and the central nervous system (spinal cord and brain). The Multifidus muscle is one of the most important stabilising muscles in your lower back. It is responsible for providing stability in your spine, but also measuring and reporting the position of your body so that all your other muscles know how and when to act.



Many studies have shown that people with low back pain lose the ability to fully activate their multifidus which in turn means there is a reduction in functional stability and control of the lumbar spine. The ReActiv8 devices consist of two leads which are placed near the medial branch of the dorsal ramus nerve. The leads are connected to a small battery powered implantable pulse generator. This implantable pulse generator creates electrical pulses which are carried by the leads to stimulate the medial branch of the dorsal ramus, causing contractions of the multifidus muscle. Over time, the stimulated activation may help your brain and body learn how to better control the muscles in between sessions. Clinical studies have shown that people with chronic low back pain who use ReActiv8, have meaningful reductions in pain and disability.

3. Will I receive the ReActiv8?

Your doctor will assess if you are a candidate for ReActiv8. If you decide not to participate in this clinical study, ReActiv8 will still be considered along with other standard care treatments for your back pain.

4. What is the study schedule, and what will I need to do if I participate?

The aim of this study is to see if your response to spinal injections can predict how you will respond to ReActiv8 therapy. The study consists of nine visits. Seven of these are part of standard care and two are in addition to standard care.

Once you agree to participate (visit 1), you will be scheduled to undergo two diagnostic spinal injections. One injection is given at the spinal level where the ReActiv8 device stimulates (i.e. where the leads are placed, visit 2). This injection is called a L2 medial branch block (see Table 1). This injection is specific to this study, and will only be performed if you are participating in the study. The second injection will be given several weeks later (visit 3). This is a standard care diagnostic technique where you will receive the same pain killing injection this time at each vertebrae level in your lumbar spine. This is called an L2-L5 medial branch block injection (see Table 1). The amount of short term pain relief you receive from each of these injections will be measured using a standard questionnaire. Based on your response to these questionnaires you will be assigned to a study treatment group. The maximum number of patients in each of these groups is 15. If you are assigned to a group that is already full, you will leave the study and go on to usual care under your doctor. Usual care may or may not include ReActiv8 therapy and is a decision made between you and your doctor.

If assigned to a group, as part of your standard care you will then have day case surgery to have the ReActiv8 implant (visit 4). Following implant, your ReActiv8 device will be activated and programming will be done (visit 5). You will also be given a patient controller and be taught how and when to use the therapy. This activation and programming visit is also part of standard care.

One month following activation and programming of the ReActiv8 implant, we will give you a telephone call to ask about your pain and to check how you are getting on with the stimulation. This telephone call is part of standard of care.

The remainder of the study schedule only involves you completing questionnaires and some simple activity tests. These questionnaires will enquire about the severity of your pain, how well you cope in everyday life, your quality of life, your employment status, your use of other medical care, the percentage reduction in pain, your overall impression of the change, and the use of pain medications. The activity tests involve timing how long it takes you to rise from a chair, walk three metres, turn, walk back three meters and sit down. We will also measure how far you can walk on a small circuit in 5 minutes. If, because of pain or other conditions, you are physically unable to complete these tests we can record it as ‘incomplete’ and record your description of what prevented you from the activity. These study visits will happen at 3, 6 and 12 months following activation of the ReActib8 implant and are part of standard care.

You may also wish to make additional appointments to reprogram the stimulation level of the device outside the recommended visits, this is a completely normal aspect of this therapy and occurs during standard care. Additional appointments can be made by contacting the hospital.

We will get in touch with your GP to let them know you are taking part in the study.

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Table 1: The study specific events occur at the following visits and involve:

Visit number	Visit name	Standard care (yes/no)	What happens at this visit
1	Enrolment	No	We will take a detailed medical history of your condition together with all medications you use for relief from your low back pain. You will also be asked to fill out some questionnaires. It will take around 30 minutes to complete these, perform some physical activity tests, and collect some baseline information about how your pain impacts your daily life.
2	L2 medial branch block injection	No	You will be given a date to attend Day Case surgery to be given a pain killing injection at the spinal level the ReActiv8 device stimulates and be asked to record your response and pain relief. This procedure takes approximately 15 minutes and will involve a small amount of x-ray radiation that we describe below. This is in addition to your normal care.
3	L2-L5 medial branch block injection	Yes	You will be given a date to attend Day Case surgery to be given a standard care diagnostic pain killing injection and be asked to record your response and pain relief.
4	Implant	Yes	You will be given a date to attend Day Case surgery to have the ReActiv8 device implanted.
5	Activation	Yes	Approximately 14 days post-implantation, you will need to come to the research clinic to have your device switched on and set up, to give you appropriate stimulation. You will be given a patient controller and taught how and when to use the ReActiv8 therapy. Please allow approximately 1 hour for this visit.
6	Month 1 telephone call	Yes	Approximately 30 days after your device has been activated, you will be asked to have a telephone call to make sure the stimulation is appropriate. You will also be asked about your pain and to check how you are getting on with the stimulation. Please allow approximately 15 minutes for this phone call.
7	Month 3	Yes	Approximately 90 days after your device has been activated, you will need to come to the research clinic to make sure the stimulation is appropriate. You will also be asked to fill in some questionnaires and perform the physical activity tests. Please allow approximately 1 hour for this visit.
8	Month 6	Yes	Approximately 180 days after your device has been activated, you will need to come to the research clinic to make sure the stimulation is appropriate. You will also be asked to fill in some questionnaires and perform the physical activity tests. Please allow approximately 1 hour for this visit.
9	Year 1	Yes	Approximately 1 year after your device has been activated, you will need to come to the research clinic to make sure the stimulation is appropriate. You will also be asked to fill in some questionnaires and perform the physical activity tests. Please allow approximately 1 hour for this visit.

5. What personal benefit will I derive from participating in the study?

If you decide to take part in this research study, there are no direct benefits for your participation. However, after some of the study treatments, you may experience benefits including a reduction in your daily pain, reduction in the amount of pain medication you need and an improvement in your quality of life.

The information gathered in this study will add to the understanding of treatment options for patients suffering from similar chronic pain in the future.

6. What risks does participation in the study entail?

If you take part in this trial, you will have two spinal, pain-killing injections and an implantation of a ReActiv8 device. One of these spinal injections will be extra to those that you would have if you did not take part in this study. In some countries it is a standard practice to do 2 diagnostic injections before a definitive treatment. This is a low risk procedure, but like everything, there are some risks involved and side effects may occur. These are usually minor.

Side effects may include;

- Mild local tenderness and/or bruising at the site of the injection that usually settles over the first few days.
- The local anaesthetic may spread causing some numbness and/or weakness in your legs and other areas. Should this occur, the effect is temporary and will rapidly resolve over minutes or sometimes hours.
- Infection. This is rare. You should seek medical help if there is local warmth or redness over the site of injection with tenderness and/or you feel hot and unwell. This may require antibiotic treatment.
- There are important nerves in the spine, but serious nerve injury is extremely rare (less than 1 in 10,000 cases).
- Injection treatments are not always effective and may not help your pain.

If you take part in this trial, you will have two spinal injections and an implantation of a ReActiv8 device. One of these spinal injections will be extra to those that you would have if you did not take part. The spinal injections and implantation procedure all use x-rays, a type of ionising radiation, to form images of your body to guide your doctor during the procedures.

Ionising radiation may cause cancer many years or decades after the exposure. We are all at risk of developing cancer during our lifetimes. 50% of the population is likely to develop one of the many forms of cancer at some stage during our lifetime. Taking part in this study may increase the chances of this happening to you to about 50.02%.

All other interventions and imaging that you will receive are standard of care for the treatment of your particular condition with this device. The remainder of the study only requires its participants to complete questionnaires and simple physical activity assessments, additional risks or side effects are not expected for participants in this study.

7. What treatment alternatives exist outside of this study?

In case you do not wish to participate to the study, you will receive the standard medical treatment according to the applicable guidelines for patients suffering from this condition. The provision of this care will not be impacted by your decision not to participate in this study.

8. Who must not participate in this study?

You cannot take part in this clinical study if you are simultaneously participating in or have recently participated in other clinical studies or clinical research projects and in case you do not fulfil the inclusion criteria for this study.

9. Will participation in the study cost me anything? Will I receive an allowance for expenses?

There is no cost to you, the procedure is covered by the NHS as medically indicated. You will have the option of having your travel expenses covered for the two visits that are made for the purposes of this research study and are not part of standard care.

10. Will I be insured during the study?

In the event that something does go wrong, and you are harmed during the study, there are no special compensation arrangements. If you are harmed and this is due to someone's negligence then you may have grounds for a legal action for compensation, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

11. Will I be informed of new information during the study?

You will be informed of new information acquired in relation to this study that may influence your willingness to continue participating in the study. You can then reflect on whether you wish to continue taking part on that basis.

12. Who decides whether I leave the study?

You can end your participation at any time without explanation and without incurring any disadvantages in your medical treatment as a result.

In certain circumstances, however, the study doctor may decide to terminate your participation in the study prematurely, and you will have no influence on this decision. Reasons for this can include that the entire study is being discontinued.

If you decide to leave the study early, or your participation is terminated prematurely for any of the reasons mentioned above, it is important for your safety that you undergo a recommended final check-up.

The study doctor will talk to you about how and where your further treatment will take place.

13. 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 _____ Research Ethics Committee

14. What will happen with my information?

How will we use information about you?

Your study doctor will need to use information from you and from your medical records for this research project, including

- NHS number
- Name
- Contact details

The team conducting this study will use this information to do the research and/or to check your records to make sure the research is being done properly. For the purposes of the study you will be allocated a unique code number so anyone outside the clinical study team who reviews the data collected, will not be able to see your personal information.

We will keep all information about you safe and secure in line with the EU General Data Protection Regulations 2018 (GDPR).

Once we have finished the study, we will keep some of the data so we can analyse the results. We will write our reports in a way that is fully anonymised, which means without revealing your name or any other information which could be used to identify you.

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?

You can find out more about how we use your information

- At www.hra.nhs.uk/information-about-patients/

- Our leaflet available from **www.hra.nhs.uk/patientdataandresearch**
- By asking one of the research team
- By sending an email to Leedsth-tr.informationgovernance@nhs.net, or
- By ringing us on 0113 2433144 and ask for the Data Protection Officer.

15. Who do I contact if I have further questions?

Consultations at the study site

You can arrange another consultation with the study doctor named on page 1 or another study doctor at any time to ask further questions about the study. They will also be happy to answer any questions about your rights and responsibilities as a patient and participant in the study.

16. Who do I contact if I have a complaint regarding the use of my personal data?

If you have a complaint about how your personal data is being processed in relation to the study, you have the right to complain to the Patient Advice and Liaison Services (PALS). However, we recommend that you contact the institution treating you in the first instance with any complaints or enquiries in regard to the use of your personal data.

Our hospital complaints is:

Patient Advice and Liaison Service: **0113 2066261**

Tel of Hospital: **0113 2432799**