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Can blocking the nerve to the back muscle predict the outcome of stimulating back muscles in managing pain due to muscle dysfunction?

Submission date
22/02/2022

Recruitment status
No longer recruiting

Registration date
24/02/2022

Overall study status
Completed

Last Edited
28/02/2025

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Chronic low back pain is a common disorder that can have a significant impact on the lives of patients. Treatment options include physiological therapy, psychological therapy and medication, which can have limited effectiveness. The multifidus muscle plays an important role in stabilising the lower back. The ReActiv8 device involves electrically eliciting contractions of the multifidus muscle to improve its strength over time and to help relieve pain. However, like most treatments, some patients respond more readily than others. This pilot study aims to explore whether responses to medial branch blocks help with predicting the benefit patients receive when treated with the ReActiv8 device.

Who can participate?
Patients aged 18 to 75 years with chronic low back pain

What does the study involve?
Participants will be recruited from one medical centre to undergo two medial branch injections. Patients who then agree to go ahead with the ReActiv8 therapy will receive insertion of the device and be placed in one of three groups according to the amount of pain relief they experienced from the medial branch injections.
Group 1 Pain reduction of ≥60% within 6 hours after bilateral L2 Medial Branch block AND pain reduction of ≥ 60% within 6hrs after bilateral L2-L5 Medial Branch block
Group 2 Pain reduction of ≥60% within 6 hours after bilateral L2 Medial Branch block OR pain reduction of ≥ 60% within 6hrs after bilateral L2-L5 Medial Branch block
Group 3 Pain reduction of less than 60% within 6 hours after bilateral L2 Medial Branch block AND pain reduction of less than 60% within 6 hours after bilateral L2-L5 Medial Branch block
Patients will be followed up 1, 3, 6 and 12 months after the ReActiv8 device has been activated.

What are the possible benefits and risks of participating?
There are no direct benefits for participation. However, after some of the study treatments,

participants may experience benefits including a reduction in their daily pain, a reduction in the amount of pain medication they need and an improvement in their 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.
Participants will have two spinal pain-killing injections and implantation of a ReActiv8 device. One of these spinal injections will be extra to those that patients would have if they did not take part in this study. In some countries it is a standard practice to do two 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:
1. Mild local tenderness and/or bruising at the site of the injection that usually settles over the first few days
2. The local anaesthetic may spread causing some numbness and/or weakness in the legs and other areas. Should this occur, the effect is temporary and will rapidly resolve over minutes or sometimes hours.
3. Infection. This is rare. Medical help should be sought if there is warmth or redness over the site of injection with tenderness and/or feeling hot and unwell. This may require antibiotic treatment.
4. There are important nerves in the spine, but serious nerve injury is extremely rare (less than 1 in 10,000 cases).
5. Injection treatments are not always effective and may not help with the pain.
The spinal injections and implantation procedure of the ReActiv8 device all use x-rays, a type of ionising radiation, to form images of the body to guide the doctor during the procedures. Ionising radiation may cause cancer years or decades after the exposure. We are all at risk of developing cancer during our lifetime. 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 about 50.02%.
All other interventions and imaging that participants will receive are standard of care for the treatment of this particular condition with this device. The remainder of the study only requires participants to complete questionnaires and simple physical activity assessments, additional risks or side effects are not expected for participants in this study.

Where is the study run from?
Leeds Teaching Hospitals NHS Trust (UK)

When is the study starting and how long is it expected to run for?
May 2020 to January 2025

Who is funding the study?
Mainstay Medical, Inc. (Ireland)

Who is the main contact?
Emma Binns, emma.binns1@nhs.net

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
295749

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 49291, IRAS 295749

Study information

Scientific 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

Study objectives
It is hypothesised that medial branch injections will have diagnostic utility for predicting response to restorative neurostimulation with the ReActiv8 device.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 03/06/2021, East of England - Cambridge Central Research Ethics Committee (Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)2071048384; cambridgecentral.rec@hra.nhs.uk), REC ref: 21/EE/0130

Study design
Non-randomized; Interventional; Design type: Treatment, Device, Complex Intervention, Rehabilitation

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Chronic low back pain

Interventions
This is a prospective observational cohort study monitoring patients up to 1 year following activation of the ReActiv8 device. Only patients who have appropriately diagnosed chronic low back pain of mechanical origin who have had no adequate symptomatic relief after at least 12 weeks of medical management will be asked to give consent to be involved.

Potential participants will be given oral and written information about the research study as well as the patient information sheet for the study. If informed consent is given, their participation in this study will be for a maximum of 1 year following activation of the ReActiv8 device.

Once the participant has signed the informed consent form, the following assessments/data will be conducted/collected:
1. Demographics
2. Medical and surgical history
3. MRI findings
4. Depression Anxiety Stress Scale (DASS)
5. Medication use

6. Numerical Rating Scale (NRS) for pain
7. Oswestry Disability Questionnaire (ODI) for pain-related disability
8. EQ-5D for health-related quality of life
9. PROMIS-29 for physical, mental and social health
10. Work status
11. Sit-stand and 5-min walk tests for physical function

Patients will then undergo L2 and L2-L5 medial branch blocks (on separate occasions) which will be followed by an assessment of pain relief and any adverse events.

If the patient agrees, they will have the ReActiv8 device implanted and activated (14 days following the implant).

1 month following activation of the ReActiv8 device, patients will receive a telephone follow-up assessment where NRS for pain and adverse events will be assessed and documented.

The following face-to-face assessments will be conducted at 3, 6 and 12 months following activation of the ReActiv8 device:
1. Adverse events assessment and documentation
2. Medication use
3. NRS for pain
4. ODI for pain-related disability
5. EQ-5D for health-related quality of life
6. PROMIS-29 for physical, mental and social health
7. Work status
8. Patient global impression of change (PGIC)
9. Patient satisfaction
10. Clinician global impression of change (CGIC)
11. Sit-stand and 5-min walk tests for physical function

Participants will be able to withdraw from the study at any time.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
ReActiv8

Primary outcome measure
1. Pain measured using the numerical rating scale (NRS) at baseline, injection 1, injection 2, and 1 month, 3 months, 6 months and 12 months post-activation of the ReActiv8 device
2. Functional disability measured using the Oswestry Disability Index (ODI) at baseline and 3 months, 6 months and 12 months post-activation of the ReActiv8 device

Secondary outcome measures
1. Health-related quality of life measured using the EQ-5D at baseline and 3 months, 6 months and 12 months post-activation of the ReActiv8 device
2. Medication use recorded using questionnaire at baseline and 3 months, 6 months and 12

months post-activation of the ReActiv8 device
3. Work status recorded using questionnaire at baseline and 3 months, 6 months and 12 months post-activation of the ReActiv8 device
4. Physical function measured using the sit-to-stand and 5-minute walk tests at baseline and 3 months, 6 months and 12 months post-activation of the ReActiv8 device

Overall study start date
20/05/2020

Completion date
31/01/2025

Eligibility

Key inclusion criteria
1. Age ≥18 years to ≤75 years
2. Chronic low back pain on the majority of days 12 weeks prior to enrolment
3. Continuing low back pain despite more than 90 days under medical management within last year

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
Planned Sample Size: 45; UK Sample Size: 45

Key exclusion criteria
Current exclusion criteria as of 31/05/2024:
1. BMI >35 kg/m²
2. Any current indication for back surgery
3. Leg pain worse than back pain or radiculopathy below the knee

Back pain exclusions:
4. Any diagnosis or correction of scoliosis
5. Neurological deficit (e.g., foot drop)
6. Sacroiliac joint pain
7. NRS of ≤5.0 and >9.0 at the Baseline Evaluation
8. ODI score <25% and >60% at enrolment

Drug use exclusions:
9. Baseline use >120 mg oral morphine equivalent per day of opioids
10. Medications not at stable dose in prior 30 days

Surgical exclusions:
11. Rhizotomy procedure of medial branch below T8 in <12 months
12. Anaesthetic block of medial branch or epidural steroids for back pain in prior 30 days
13. Previous back surgery below T8
14. Previous destructive thoracic or lumbar sympathectomy

Psycho-social exclusions:
15. Current/pending litigation, claim or monetary settlement
16. Closed claim in past five years, or financial incentive to remain impaired
17. Current active depression

Previous exclusion criteria:
1. BMI >35 kg/m²
2. Any current indication for back surgery
3. Leg pain worse than back pain or radiculopathy below the knee
4. Any diagnosis or correction of scoliosis
5. Neurological deficit (e.g. foot drop)
6. Sacroiliac joint pain
7. NRS ≤5.0 and >9.0 at baseline
8. ODI score <25% and >60% at enrolment
9. PainDETECT score >19 at enrolment
10. Baseline use >120 mg oral morphine equivalent per day of opioids
11. Medications not at stable dose in prior 30 days
12. Rhizotomy procedure of medial branch below T8 in < 12 months
13. Anaesthetic block of medial branch or epidural steroids for back pain in prior 30 days
14. Previous back surgery below T8
15. Previous destructive thoracic or lumbar sympathectomy
16. Current/pending litigation, claim or monetary settlement
17. Closed claim in past five years, or financial incentive to remain impaired
18. Current active depression

Date of first enrolment
01/02/2022

Date of final enrolment
31/12/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Leeds General Infirmary
Great George Street
Leeds
United Kingdom
LS1 3EX

Sponsor information

Organisation
Leeds Teaching Hospitals NHS Trust

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Sponsor type
Hospital/treatment centre

Website
http://www.leedsth.nhs.uk/home/

ROR
https://ror.org/00v4dac24

Funder(s)

Funder type
Industry

Funder Name
Mainstay Medical, Inc.

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal and presented at national and/or international conferences

Intention to publish date
31/08/2025

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2.1	25/11/2021	23/02/2022	No	Yes
HRA research summary			20/09/2023	No	No