ISRCTN16473239 https://doi.org/10.1186/ISRCTN16473239

Radiofrequency denervation for low back pain

Submission date
17/08/2021

Recruitment status
Recruiting

Registration date
09/11/2021

Overall study status
Ongoing

Last Edited
15/07/2025

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Long-term low back pain is common, affecting 10-15% of adults. It can significantly impair the health, mood, and daily lives of people who have it. One type of low back pain is caused by the small joints between the bones in the lower back. Treatments include painkillers, exercise and talking therapies. However, if people do not get better with these treatments, they can be offered radiofrequency “denervation”. Denervation involves placing a needle in the nerve to the painful joint, which is heated up to cause a break in the nerve. The purpose of this is to stop the nerve from sending pain messages to the brain. Denervation is low risk and is used widely in the National Health Service (NHS) but it is not known if this procedure definitely reduces pain or is a good way to spend NHS money. This study aims to find out if denervation reduces low back pain and is good value for money.

Who can participate?
Patients aged 18 years or older with chronic moderate to severe low back pain who are eligible for radiofrequency denervation treatment

What does the study involve?
Participants are randomly allocated into one of two groups. Half will have the denervation and half will have a placebo treatment, which involves placement of the needle in the nerve but without heating it up so the nerve is not affected. Participants whose symptoms do not improve after 3 months will be offered the chance to receive the other treatment. This means that patients who had no improvement because they had the placebo treatment first would have the opportunity for denervation the second time. Participants will be asked questions about their low back pain, ability to carry out daily tasks including their work, their general health, and mental well-being over the next 2 years. Information will also be collected to find out if denervation is good value for money.

What are the possible benefits and risks of participating?
There are no guaranteed benefits of participating, but the results from this study may help improve the treatment of people with low back pain in the future. The risks associated with taking part in this study are the same as the risks of having this procedure as part of usual care, and are the same for both the denervation and the placebo treatment. However, if participants do not experience an improvement in pain after 3 months, they will be offered the chance to receive the other treatment. Therefore, there is the possibility that participants will have two

procedures (denervation and placebo treatment). The procedure is low risk and serious side effects are rare.

Where is the study run from?
University of Bristol (UK)

When is the study starting and how long is it expected to run for?
August 2018 to September 2025

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Vikki Wylde (Chief Investigator) or Kate Ashton (Trial Manager)
radical-study@bristol.ac.uk

Contact information

Type(s)
Public

Contact name
Ms Kate Ashton

ORCID ID
https://orcid.org/0000-0002-9163-0512

Contact details
Bristol Trials Centre
Bristol Medical School
University of Bristol
1-5 Whiteladies Road
Bristol
United Kingdom
BS8 1NU

Type(s)
Scientific

Contact name
Dr Vikki Wylde

ORCID ID
https://orcid.org/0000-0002-8460-1529

Contact details
Musculoskeletal Research Unit
Translational Health Sciences
Bristol Medical School
University of Bristol
Learning and Research Building

Southmead Hospital
Bristol
United Kingdom
BS10 5NB

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
285322

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 46543, IRAS 285322, NIHR127457

Study information

Scientific Title
Radiofrequency denervation for chronic and moderate to severe low back pain (RADICAL)

Acronym
RADICAL

Study objectives
Radiofrequency denervation compared to a placebo treatment reduces the severity of pain at 3 months after the intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 30/07/2021, London - Fulham Research Ethics Committee (Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0)207 104 8035; fulham.rec@hra.nhs.uk), REC ref: 21/LO/0471

Study design
Randomized; Both; Design type: Treatment, Other, Qualitative

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Chronic and moderate to severe low back pain

Interventions
Trial participants will be randomised in a 1:1 ratio to receive either radiofrequency denervation (RFD) of the lumbar medial branches of the dorsal rami; or placebo treatment, which will follow the same protocol, but the electrode tip temperature will not be raised.

Randomisation will be performed by a member of the theatre staff, not involved in participant follow-up, via a secure internet-based randomisation system ensuring allocation concealment. Participants will be allocated in a 1:1 ratio to RFD or placebo treatment. The allocation, prepared by a statistician independent of the trial team, will be computer-generated and blocked with varying block sizes. Randomisation will be stratified by operator to ensure that any operator effect is distributed equally across groups.

Participants who do not experience a clinically meaningful improvement in pain 3 months after randomisation will be offered “repeat RFD” but with the alternative intervention to the one provided at the outset without disclosing the original allocation.

Intervention Type
Procedure/Surgery

Primary outcome measure
Patient-reported low back pain (LBP) pain severity over the past week, measured using a 0-10 pain Numeric Rating Scale (NRS); Timepoint(s): 3 months post-randomisation

Secondary outcome measures
1. Functional disability measured using the Oswestry Disability Index (ODI) version 2.1b at baseline, 3, 6, 12, 18 and 24 months post randomisation
2. Health-related quality of life (HRQoL) measured using EQ-5D-5L at baseline, 6 weeks, and 3, 6, 12, 18 and 24 months post randomisation
3. General health measured using SF-12 Physical Component Score at baseline, 3, 6, 12, 18 and 24 months post randomisation
4. Mental health measured using SF-12 Mental Component Score at baseline, 3, 6, 12, 18 and 24 months post randomisation
5. Time to pain recovery measured using time from randomisation until the first timepoint at which the patient reports a pain reduction of ≥60% that remains at ≥60% lower than baseline at their subsequent timepoint. Pain severity over the past week will be measured using a 0-10 pain Numerical Rating Scale (NRS), administered at baseline, 2, 4, 6, 8 and 10 weeks, and 3, 6, 12, 18 and 24 months post randomisation.
Updated 08/07/2024: Pain severity over the past week will be measured using a 0-10 pain Numerical Rating Scale (NRS), administered at baseline, 2 and 6 weeks, and 3, 6, 12, 18 and 24 months post randomisation

6. Uptake of offer for repeat RFD. This will be offered to participants who are eligible 3 months after randomisation and can be taken up by participants up to 24 months
7. Satisfaction with treatment outcome measured using Likert scale at 3, 6, 12, 18 and 24 months post randomisation
8. Adverse events measured using active capture of adverse events at 2 and 6 weeks, and 3, 6, 12, 18 and 24 months post randomisation
9. Work outcomes: Work status and days lost from work and usual activities due to LBP measured using the Work Productivity and Activity Impairment (WPAI) questionnaire at baseline, 3, 6, 12, 18 and 24 months post randomisation
10. Healthcare utilisation, including medications, measured using a patient-reported resource use questionnaire at baseline, 3, 6, 12, 18 and 24 months post randomisation, and medical records

Overall study start date
22/08/2018

Completion date
30/09/2026

Eligibility

Key inclusion criteria
Current inclusion criteria as of 22/05/2023:
1. 18 years of age or older
2. LBP is the primary source of pain
3. Positive response to a single diagnostic MBB with no steroids administered
4. Chronic LBP (>3 months duration), assumed due to the fact patient was listed for MBB
5. Moderate to severe LBP (pain NRS score ≥5 on Baseline Questionnaire)
6. Listed for RFD by their clinical care team

Previous inclusion criteria:
1. 18 years of age or older
2. Chronic moderate to severe LBP (>3 months duration, pain NRS score ≥5 for usual pain over the past week at the time of screening)
3. LBP is the primary source of pain
4. Referred to a pain or spinal clinic
5. Listed for MBB by their clinical care team (due to clinical suspicion or clinical features suggesting that the main source of LBP is from a facet joint)
6. Positive response to a single diagnostic MBB with 1 ml or less of local anaesthetic at each level (no steroids)
7. Listed for RFD by their clinical care team

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 180; UK Sample Size: 180

Key exclusion criteria
Current exclusion criteria as of 22/05/2023:
1. Known pregnancy
2. Severe depression (Hospital Anxiety and Depression Scale (HADS) depression score >= 15)
3. Known previous RFD
4. Known previous back surgery where metal-work has been used in the lumbar spine
5. Pacemaker or implantable cardioverter-defibrillator
6. Clinical suspicion that an alternative diagnosis is the reason for low back pain (as defined by NICE, including, but not limited to: metastatic spinal cord compression, spinal injury, spondyloarthritis, or cancer)
7. Prisoner
8. Patient lacks capacity to consent
9. Existing co-enrolment in another clinical study if: i) the intervention in the other study is expected to influence the primary outcome (this will be considered by a senior clinician on a case-by-case basis); ii) it is considered too burdensome for the patient; or iii) it is not permitted by the other study

Previous exclusion criteria:
1. Known pregnancy
2. Unwilling or unable to tolerate procedure
3. Severe depression (Hospital Anxiety and Depression Scale (HADS) depression score >= 15)
4. Known previous RFD
5. Known previous back surgery where metal-work has been used in the lumbar spine
6. Pacemaker or implantable cardioverter-defibrillator
7. Clinical suspicion that an alternative diagnosis is the reason for low back pain (as defined by NICE, including, but not limited to: metastatic spinal cord compression, spinal injury, spondyloarthritis, or cancer)
8. Prisoner
9. Patient lacks capacity to consent
10. Existing co-enrolment in another clinical study if: i) the intervention in the other study is expected to influence the primary outcome (this will be considered by a senior clinician on a case-by-case basis); ii) it is considered too burdensome for the patient; or iii) it is not permitted by the other study

Date of first enrolment
16/03/2022

Date of final enrolment
31/12/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St. James's University Hospital
Beckett Street
Leeds
United Kingdom
LS9 7TF

Study participating centre
Queen Elizabeth Hospital
Mindelsohn Way
Edgbaston
Birmingham
United Kingdom
B15 2GW

Study participating centre
Southmead Hospital
Southmead Road
Westbury-On-Trym
Bristol
United Kingdom
BS10 5NB

Study participating centre
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre
Kings Mill Hospital
Mansfield Road
Sutton-In-Ashfield
United Kingdom
NG17 4JL

Study participating centre
Solent NHS Trust
Highpoint Venue
Bursledon Road
Southampton
United Kingdom
SO19 8BR

Study participating centre
Walsgrave General Hospital
Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX

Study participating centre
The Royal London Hospital
80 Newark Street
London
United Kingdom
E1 2ES

Study participating centre
The Walton Centre
Lower Lane
Liverpool
United Kingdom
L9 7LJ

Study participating centre
James Cook University Hospital
Marton Road
Middlesbrough
United Kingdom
TS4 3BW

Study participating centre
Freeman Hospital
Freeman Road
High Heaton
Newcastle upon Tyne

United Kingdom
NE7 7DN

Study participating centre
NHS Grampian
Summerfield House
2 Eday Road
Aberdeen
United Kingdom
AB15 6RE

Study participating centre
Royal Berkshire Hospital
London Road
Reading
United Kingdom
RG1 5AN

Study participating centre
City Hospital
Dudley Road
Birmingham
United Kingdom
B18 7QH

Study participating centre
Epsom and St Helier University Hospitals NHS Trust
St Helier Hospital
Wrythe Lane
Carshalton
United Kingdom
SM5 1AA

Study participating centre
Liverpool University Hospitals NHS Foundation Trust
Royal Liverpool University Hospital
Prescot Street
Liverpool
United Kingdom
L7 8XP

Study participating centre
Royal Orthopaedic Hospital
The Woodlands
Bristol Road South
Northfield
Birmingham
United Kingdom
B31 2AP

Study participating centre
Lancashire Teaching Hospitals NHS Foundation Trust
Royal Preston Hospital
Sharoe Green Lane
Fulwood
Preston
United Kingdom
PR2 9HT

Study participating centre
Sherwood Forest Hospitals NHS Foundation Trust
Kings Mill Hospital
Mansfield Road
Sutton-in-ashfield
United Kingdom
NG17 4JL

Study participating centre
Whittington Health NHS Trust
The Whittington Hospital
Magdala Avenue
London
United Kingdom
N19 5NF

Study participating centre
East Kent Hospitals University NHS Foundation Trust
Kent & Canterbury Hospital
Ethelbert Road
Canterbury
United Kingdom
CT1 3NG

Study participating centre
The Royal Orthopaedic Hospital NHS Foundation Trust
The Woodlands
Bristol Road South
Northfield
Birmingham
United Kingdom
B31 2AP

Study participating centre
Solent NHS Trust
Solent NHS Trust Headquarters
Highpoint Venue
Bursledon Road
Southampton
United Kingdom
SO19 8BR

Sponsor information

Organisation
North Bristol NHS Trust

Sponsor details
Southmead Hospital
Southmead Road
Westbury-On-Trym
Bristol
England
United Kingdom
BS10 5NB
+44 (0)117 414 9330
researchsponsor@nbt.nhs.uk

Sponsor type
Hospital/treatment centre

Website
https://www.nbt.nhs.uk/research-innovation

ROR
https://ror.org/036x6gt55

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: NIHR127457

Results and Publications

Publication and dissemination plan
The researchers will be publishing the protocol in a peer-reviewed journal. It will also be available on the HTA website, once it has been fully approved by the HRA.

The findings will be disseminated by usual academic channels, i.e. presentation at international meetings, as well as by peer-reviewed publications (including a full report to the NIHR Health Technology Assessment (HTA) programme) and through patient organisations and newsletters to patients, where available.

Intention to publish date
31/12/2024

Individual participant data (IPD) sharing plan
Data will not be made available for sharing until after the publication of the main results of the study. Thereafter, anonymised individual patient data will be made available for secondary research, conditional on assurance from the secondary researcher that the proposed use of the data is compliant with the MRC Policy on Data Sharing regarding scientific quality, ethical requirements and value for money. A minimum requirement with respect to scientific quality will be a publicly available pre-specified protocol describing the purpose, methods and analysis of the secondary research, e.g. a protocol for a Cochrane systematic review. Anonymised recruitment consultation and interview transcripts may also be used to support the teaching of qualitative research methods. Please contact Vikki Wylde using the following email: radical-study@bristol.ac.uk.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Protocol article		27/07/2024	29/07/2024	Yes	No