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FORENSIC-UK: Fusion versus Best Conservative Care

Submission date 27/03/2025	**Recruitment status** Recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 04/04/2025	**Overall study status** Ongoing	
Last Edited 01/07/2025	**Condition category** Musculoskeletal Diseases	

Plain English summary of protocol

Background and study aims
Low back pain is common for many people and often improves without specific treatment. However, for some people their low back pain does not go away, and the use of painkillers and physiotherapy (which we call non-surgical treatment) is often successful as the first line of treatment. There has also been good research to show that this treatment is beneficial. However, this approach does not work for everyone, and some people are left with ongoing severe low back pain impacting their health, daily activities and work. Some medical professionals think that an operation called spinal fusion may help. The study aims to investigate whether treating low back pain with surgery is better than using non-surgical treatment for patients with long-standing back pain that has not responded to previous non-surgery treatment, and also whether the spinal fusion surgery is good value for money for the NHS.

Who can participate?
Participants can join the study if they:
1. Have severe and ongoing low back pain for 6 months or more
2. Have had some non-surgical care to help with back pain in the past 6 months or more, which has been unsuccessful
3. Are aged between 18 and 65 years
4. Suitable to receive either spinal fusion surgery or the best conservative care

What does the study involve?
Participants will be randomly allocated to either Spinal Fusion Surgery or personalised Best Conservative Care.
Spinal Fusion Surgery: this group will receive Spinal Fusion Surgery, an operation to surgically fix the spinal bones together in their lower back.
Best Conservative Care: this group will undergo a personalised non-surgical treatment plan which will be specially created for the patient using a shared decision-making tool between the treating clinician and the participant. It can include checking and maybe adjusting the participants' current medication, exercise, self-management, pain control, and signposting to other NHS services. Participants will be asked to complete questionnaires relating to their treatment, pain and quality of life at 6,12 and 24 months. Participants will be able to complete questionnaires electronically or on paper according to their preference.

What are the possible benefits and risks of participating?
The benefits of taking part are that participants' back pain may improve, and that physiotherapy or pain relief may no longer be required following either spinal fusion surgery or best conservative care.
For all participants, the risks are that the pain may not improve and the side effects of medication. Also, there is exposure to a low-level magnetic field if you have an MRI scan, or low-level radiation due to the CT/SPECT scan, to check if you are suitable for this study. For those receiving surgery, there are the risks associated with any operation (e.g. bleeding from the wound site) and general anaesthetic (e.g. nausea, headache), and exposure to low-level radiation due to the CT scan at 2 years post-surgery. For those receiving best conservative care, there is a risk of increased pain associated with exercise. All procedures used in this study are known in the NHS and deemed safe.

Where is the study run from?
The study is managed by the Surgical Intervention Trials Unit (SITU), Oxford Clinical Trials Research Unit (OCTRU), University of Oxford (UK). The study is sponsored by the University of Oxford

When is the study starting and how long is it expected to run for?
October 2024 to September 2026

Who is funding the study?
National Institute for Health and Care Research (NIHR) Health Technology Assessment (HTA) Programme (UK)

Who is the main contact?
Study team contact, forensic@ndorms.ox.ac.uk
Prof. David Beard, david.beard@ndorms.ox.ac.uk

Study website
https://forensic.octru.ox.ac.uk/forensic/homepage

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
343826

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 66893, Grant Code: NIHR134859

Study information

Scientific Title
FORENSIC-UK: The clinical and cost-effectiveness of lumbar fusion surgery for patients with persistent, severe low back pain

Acronym
FORENSIC-UK

Study objectives
The aim of FORENSIC-UK is to test for superiority of lumbar fusion surgery (LFS) versus continued best conservative care (BCC) (non-surgical) on disability (physical function) in patients with severe persistent low back pain and lumbar degenerative disease, and to investigate the cost-effectiveness of LFS compared with continued BCC.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 19/03/2025, East of England - Cambridge East Research Ethics Committee (2 Redman Place, London, EC20 1JQ, UK; +44 (0)20 7104 8096; CambridgeEast.REC@hra.nhs.uk), ref: 25/EE/0040

Study design
Randomized; Interventional; Design type: Treatment, Education or Self-Management, Imaging, Physical, Surgery, Rehabilitation

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Low back pain

Interventions
The design of the study is a randomised controlled trial with a recruitment target of 270 patients who have had and still have persistent LBP for 6 months or more. (It is crucial for this study that patients have tried the current recommended conservative non-surgery standard NHS treatments before they are considered for spinal fusion surgery, thereby reserving LFS for patients who have not had a good response from their previous conservative care.)

Following consent the patients would be randomised in a ratio of 1:1, thus giving 135 participants to each arm of the study (lumbar fusion surgery [LFS] versus continued best conservative care [BCC]). Participants will not be blinded in this study due to the nature of a non-surgery arm and surgery arm.

Participants allocated to best conservative care will have individual “tailoring” of their care (to make it the very best possible).

Over a 24-month period we will ask patients about their physical function, pain, mental health, general health, quality of life, days off work, intervention adherence and healthcare use.

We will ask measured, validated and carefully designed sets of questionnaires that will include: Low Back Pain intensity using the Numerical Rating Scale(NRS) sent to participants monthly via SMS text messaging, email or by post in a paper form. Paper or electronic links (participant preference) to Questionnaires at the beginning(Baseline), 6, 12 and 24 months will be sent to each participant and will include: the Oswestry Disability Index (ODI) which will measure our Primary Outcome, quality of life (EQ-5D-5L), Depression (PHQ8), Fear Avoidance Beliefs (TSK), Self-efficacy Beliefs (PSEQ), Global Perceived Effect (GPE) work outcomes (days-off-work), Heath-care Resource Use and treatment satisfaction (only at 24m). Any adverse events, revision /further surgery, fusion failure rate, healthcare use (NHS and non-NHS), including surgery, conservative care, and concurrent treatments (including analgesia) will be collected via clinical forms.

We have built into the study an internal pilot stage to recruit 45 participants in the first 10 months over 8-10 sites to test the recruitment and retention process of the study. We are using a Stop/Go assessment at the end of the Pilot phase to assess the feasibility of the study.

In addition to this we have integrated a QRI Information study with the University of Bristol using a two-phase assessment: Phase 1 to assist in the design and development of the study, and Phase 2 to assist in the delivery and (if required) aid recruitment to the study.

Intervention Type

Procedure/Surgery

Primary outcome measure
Low back pain (LBP) related physical function is measured using the Oswestry Disability Index (ODI) at 24 months

Secondary outcome measures
1. Low back pain (LBP) intensity is measured monthly using the Numerical Rating Scale (NRS on a scale 1-10)
2. Low back pain (LBP) related physical function is also measured using the Oswestry Disability Index (ODI) at baseline, 6 and 12 months
3. Cost-effectiveness will be measured with:
3.1. Quality of Life using the EQ-5D-5L at baseline, 6, 12 and 24 months
3.2. Pain Self-efficacy Questionnaire (PSEQ) at baseline, 6, 12 and 24 months
3.3. Patient Health Questionnaire (PHQ-8) at baseline, 6, 12 and 24 months
3.4. Tampa Scale of Kinesiophobia (TSK) at baseline, 6, 12 and 24 months
3.5. Global Perceived Effect Scale (GPE) at baseline, 6, 12 and 24 months
3.6. Healthcare Resources Use at baseline, 6, 12 and 24 months
3.7. Work status at baseline, 6, 12 and 24 months
3.8. Treatment Satisfaction at 24 months

Overall study start date
01/10/2024

Completion date
30/09/2026

Eligibility

Key inclusion criteria
1. Aged 18 to 65 years
2. Episode of Low Back Pain (lasting >=6 months)
3. Low Back Pain is >=6 on a 0-10 Numerical Rating Score (NRS)
4. Have undergone previous non-surgery treatment that aligns with best practice guidelines (National Institute of Health and Care Excellence. Low back pain and sciatica in over 16s: assessment and management (Clinical Guideline [NG59]) London 2016. Sect. 1.9), e.g.:
4.1. A course of physical therapy
4.2. A course of psychological therapy
4.3. A course of treatment from a multi-disciplinary team
4.4. A course of treatment from specialist medical care
4.5. Medial branch blocks/radiofrequency denervation
4.6. Analgesia
5. Willing and able to provide informed consent
6. Recent evidence (within the last 12 months) of lumbar degenerative disease using appropriate imaging (Magnetic Resonance Imaging [MRI] +/- Single Photon Emission Computed Tomography /Computed Tomography [SPECT/CT), +/- previous discectomy/decompression
7. Suitable for both lumbar fusion surgery (LFS) at 1 or 2 lumbar spine levels and best conservative care (BCC)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
Planned Sample Size: 270; UK Sample Size: 270

Key exclusion criteria
1. Has low-back related leg pain more severe than low back pain, e.g. claudication
2. Pain in any other body region more severe than low back pain
3. Previous (or attempted) LFS
4. Has psychiatric disorders (e.g. diagnosed personality disorders, post-traumatic stress disorder, drug or alcohol abuse/addiction, diagnosis of severe depression).
5. Radiculopathy or claudication or clinical signs of nerve decompression where the treatment plan includes offering a direct or indirect decompression along with the fusion
6. Any other reasons indicated for lumbar fusion surgery (LFS), e.g. deformity, infection, tumours, instability (due to spondylolisthesis of grade 2 or above), spinal fracture, systematic inflammatory disease

Date of first enrolment
30/06/2025

Date of final enrolment
30/09/2026

Locations

Countries of recruitment
England

Northern Ireland

United Kingdom

Wales

Study participating centre
Sheffield Teaching Hospitals NHS Foundation Trust
Northern General Hospital
Herries Road

Sheffield
United Kingdom
S5 7AU

Study participating centre
Belfast Health and Social Care Trust
Trust Headquarters
A Floor - Belfast City Hospital
Lisburn Road
Belfast
United Kingdom
BT9 7AB

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

Study participating centre
University College London Hospitals NHS Foundation Trust
The National Hospital for Neurology and Neurosurgery
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Study participating centre
University Hospitals Coventry and Warwickshire NHS Trust
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Study participating centre
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London House
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RG12 2UT

Study participating centre
Whittington Health NHS Trust
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Northumbria Way
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Study participating centre
Somerset NHS Foundation Trust
Trust Management
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Taunton
United Kingdom
TA1 5DA

Study participating centre
The Royal Wolverhampton NHS Trust
New Cross Hospital

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University Hospitals of Derby and Burton NHS Foundation Trust
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Sponsor type
University/education

Website
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ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The findings will be published in a high-impact peer-reviewed journal and will be disseminated across the clinical community and NICE. Study papers will be published in high-impact factor journals and will be made available under open access so that high visibility of the work can be maintained as per the NIHR policy.

Intention to publish date

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?
Protocol file	version 2.0	14/03/2025	03/04/2025	No	No
Protocol (preprint)		26/05/2025	30/06/2025	No	No
Participant information sheet	version 3.0	30/04/2025	01/07/2025	No	Yes
Participant information sheet	version 2.0	12/03/2025	01/07/2025	No	Yes