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QUeen Elizabeth physiotherapy post lumbar discectomy STudy: a pilot and feasibility trial - QUEST

Submission date
09/11/2012

Recruitment status
No longer recruiting

Registration date
18/12/2012

Overall study status
Completed

Last Edited
13/02/2017

Condition category
Surgery

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
At some time in their life, 60% to 80% of people will have low back problems and surgery for its treatment is the greatest cost to the NHS. Lumbar discectomy surgery is a common procedure for patients with pain in their legs. However, 30-70% of patients continuing to have problems even after the surgery. Recovery after surgery is, therefore, an important area to research. Currently, treatment following lumbar discectomy comprises a patient leaflet or physiotherapy or both. Practice varies across hospitals and it is unknown whether providing a patient leaflet and physiotherapy benefits patients' recovery compared with use of a patient leaflet alone. This is why we are conducting the study. This study is conducted to help us improve the design and prospects to do a future larger study.

Who can participate?
Men and women aged over 18 who have recently undergone the first lumbar discectomy surgery

What does the study involve?
All participants are asked to attend two assessment clinics at 4 and 16 weeks after surgery and half the participants at each hospital are asked to attend a third assessment clinic at 30 weeks after surgery. Assessments comprise of a short questionnaire and two simple physical tests that assess how well patients can move their back and legs. Patients are randomly allocated one of the following groups: patient leaflet and individual outpatient physiotherapy, or patient leaflet alone; and 30-week follow-up, or not. Participants allocated to receive individual outpatient physiotherapy and the patient leaflet receive up to 8 treatment sessions with a physiotherapist, starting as soon as possible after the 4-week assessment clinic. At their final assessment visit, participants are invited to attend a meeting with other participants who received the same treatment, to discuss their experience.

What are the possible benefits and risks of participating?
We cannot promise that taking part in the study will help the participants, but the information obtained could help them and patients like them in the future. All participants receive a copy of a Patient Leaflet that has been designed specifically for patients following lumbar discectomy

surgery. The leaflet contains information about the patient's back, surgery and recovery after surgery. There are no known risks of taking part in the study.

Where is the study run from?
Queen Elizabeth Hospital Birmingham (UK) and Salford Royal NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
Recruitment for the study started in January 2013. Participants will be enrolled on the study for 7 months.

Who is funding the study?
Queen Elizabeth Hospital Birmingham Charity (UK)

Who is the main contact?
Dr Alison Rushton
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Contact information

Type(s)
Scientific

Contact name
Dr Alison Rushton

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1

Study information

Scientific Title
QUeen Elizabeth Physiotherapy post lumbar discectomy STudy: a feasibility and pilot phase II trial to inform the development of a future phase III randomised controlled trial (QUEST)

Acronym
QUEST

Study objectives
One to one physiotherapy plus the Patient Leaflet will be more beneficial than the Patient Leaflet (phase II trial)

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Midlands - Solihull Research Ethics Committee, 25/09/2012, ref: 12/WM/0224

Study design
Pilot/feasibility study of a randomised controlled trial with two arms

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 patient information sheet

Health condition(s) or problem(s) studied
Rehabilitation following lumbar spinal surgery

Interventions
1. Up to 8 sessions of individualised 1-1 physiotherapy over an 8-week period; treatment in-line with pre-defined framework for decision-making; starting approximately 4 weeks post surgery AND specifically designed patient leaflet
2. Specifically designed patient leaflet

Intervention Type
Behavioural

Primary outcome measure
Roland Morris Disability Questionnaire (0 to 24)

Secondary outcome measures
1. Global Perceived Effect scale (0 to 7)
2. VAS back pain (0 to 10cm) & VAS leg pain (0 to 10cm)
3. Straight Leg Raise (cm)
4. Time to return to work / normal function / full duty (as relevant) from date of operation
5. EQ-5D 5L
6. Tampa Scale for Kinesiophobia (fear of movement)
7. Fear avoidance and beliefs questionnaire
8. Range of lumbar movement
9. Use of medication
10. Re-operation
11. Level of compliance with exercises

Overall study start date
26/10/2012

Completion date
26/05/2014

Eligibility

Key inclusion criteria
1. Male and female patients aged >18 years
2. Post primary, single level, lumbar discectomy (including microdiscectomy)
3. Ability to communicate in English

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
70

Key exclusion criteria
1. Previous surgery at the same spinal level
2. Co-morbidities that might impact on ability to participate in study interventions e.g. neurological disorders, cognitive dysfunction, uncontrolled cardiovascular disease, osteoporotic fracture, spondylolythesis, MS, tumour
3. Complications from surgery e.g. excessive bleeding, severe intra-operative root damage, level error, or severe wound infection that would prevent participation in either intervention
4. Participation in a concurrent trial

Date of first enrolment
13/01/2013

Date of final enrolment
26/05/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Birmingham
Birmingham
United Kingdom
B15 2TT

Sponsor information

Organisation
University of Birmingham (UK)

Sponsor details
Research Governance Team
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Sponsor type
University/education

Website
http://www.birmingham.ac.uk/researchsupportgroup

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Charity

Funder Name
Queen Elizabeth Hospital Birmingham Charity (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	12/11/2015		Yes	No
Results article	results	09/11/2016		Yes	No