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Early physiotherapy for chronic low back pain patients

Submission date
02/08/2020

Recruitment status
No longer recruiting

Registration date
04/08/2020

Overall study status
Completed

Last Edited
06/09/2023

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Low Back Pain (LBP) is a very common symptom experienced by a high number of the population. Mostly, LBP symptoms resolve with time or conservative treatment. It has been proposed that imaging, MRI mainly, can negatively impact patient's recovery in terms of high consumption of pain killers, frequent visits to the doctors and elevating the anxiety and fear of the patients. This study is set to examine whether providing physiotherapy in secondary care level hospitals instead of MRI imaging is feasible and acceptable.

Who can participate?
Patients with non-specific LBP, no underlying serious pathology, who are referred to spine clinics in a secondary care center in Riyadh, Saudi Arabia aged from 18-65. There should be no recorded of MRI or physiotherapy in the past 6 months.

What does the study involve?
The patients will be randomized into two groups. the first group will be referred to have physiotherapy immediately. the second group (routine practice) will have MRI for their spine then discuss the result with the doctor before being referred to physiotherapy.

What are the possible benefits and risks of participating?
There are no expected benefits or associated risks from participating in this study.

Where is the study run from?
King Fahad Medical City (Saudi Arabia)

When is the study starting and how long is it expected to run for?
October 2015 to July 2018

Who is funding the study?
Saudi Spine Society (Saudi Arabia)

Who is the main contact?
Dr Ahmed Alhowimel, a.alhowimel@psau.edu.sa

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Feasibility study and process evaluation of MRI plus physiotherapy vs. physiotherapy alone in non-specific chronic low back pain among patients in Saudi Arabia

Study objectives
It is not known whether altering the practice of routine MRI use in Saudi Arabia would be acceptable to healthcare practitioners and patients and lead to improved psychosocial and disability outcomes. Therefore, this study will seek to examine the feasibility and acceptability of conducting an RCT to answer the following question: Does MRI diagnosis negatively influence psychosocial and disability outcomes in patients with CLBP who are undergoing physiotherapy?

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 21/12/2016, Research Ethics Committee of the Faculty of Medicine and Health Science at the University of Nottingham (Medical School, Queen's Medical Centre Campus, Nottingham, NG7 2UH; louise.sabir@nottingham.ac.uk; +44(0)115 8232561), ref: OVS 18082016
2. Approved 21/11/2016, King Fahad Medical City (Riyadh, Saudi Arabia; +966 12889999; okasule@kfmc.med.sa), ref: H-01-R-R-012

Study design
Single-center two-arm non-inferiority feasibility randomized controlled trial

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
Chronic low back pain

Interventions
MRI+ Physiotherapy
Participants allocated to the MRI group were sent for an MRI scan of the lumbar spine, and a follow-up visit was planned to discuss the results. The time interval to undergo MRI ranged from 3 to 6 weeks. After discussing the results with their doctor, the patients were referred to physiotherapy. Next, another copy of the questionnaire booklet was completed by the participants after finishing the physiotherapy treatment, which lasted for a period of 2 weeks to 4 weeks.

Early Physiotherapy
Following allocation participants in the control arm (namely, the non-MRI group) were immediately asked to complete the booklet of questions and standard questionnaires. Participants were then referred to a physiotherapist for treatment, and the time required to initiate physiotherapy ranged from 1 week to 2 weeks. After completing the physiotherapy treatment programme, which lasted for 2 weeks to 4 weeks, the second assessment was taken

Intervention Type
Behavioural

Primary outcome measure
The feasibility and acceptability of a large scale RCT:
1. Recruitment: Recruit at least 24 participants

2. Follow-up: If there is no more than 20% of loss to follow-up
3. Acceptability: If most participants interviewed stated that randomisation is acceptable and if at least 65% of eligible patients consent to participate in the trial

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/10/2015

Completion date
29/07/2018

Eligibility

Key inclusion criteria
1. Aged 18 – 65 years
2. Complaint of CLBP with no clear medical diagnosis (malignancy, fracture, infection, spinal stenosis, spondylolisthesis, or inflammatory disease)
3. Pain persisting for more than 3 months

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
The sample size (n=36) was calculated from the number of patients matching the inclusion criteria who visited spine clinics in the 3 months prior to conducting the study. The estimated non-consent rate of 50%, suggested 6 new patients to be randomized per month.

Total final enrolment
16

Key exclusion criteria
1. Pregnancy
2. New mother <6 months postpartum
3. Those who had undergone pain-relieving procedures (injection or denervation) in the previous

3 months
4. Those who showed evidence of neurological impairment specific to LBP and received physiotherapy treatment for their LBP and/or MRI scan in the last 6 months prior to recruitment

Date of first enrolment
01/03/2018

Date of final enrolment
24/07/2018

Locations

Countries of recruitment
Saudi Arabia

Study participating centre
King Fahad Medical City
Kurais Street
Riyadh
Saudi Arabia
12231

Sponsor information

Organisation
Saudi Spine Society

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Sponsor type
Other

Website
http://saudispine.org/

Funder(s)

Funder type
Research organisation

Funder Name
Saudi Spine Society

Results and Publications

Publication and dissemination plan
Planned publication in high-impact peer-reviewed journal.

Intention to publish date
01/09/2020

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Preprint results		09/03/2020		No	No
Protocol file			07/08/2020	No	No
Results article		30/11/2020	06/09/2023	Yes	No