

Early physiotherapy for chronic low back pain patients

Submission date 02/08/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 04/08/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 06/09/2023	Condition category Musculoskeletal Diseases	<input type="checkbox"/> 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

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

There are no secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

65 years

Sex

All

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

Funder(s)

Funder type
Research organisation

Funder Name
Saudi Spine Society

Results and Publications

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?
Results article		30/11/2020	06/09/2023	Yes	No
Preprint results		09/03/2020		No	No
Protocol file			07/08/2020	No	No