ISRCTN75779521 https://doi.org/10.1186/ISRCTN75779521

Novel pre-surgery exercise in patients waiting for a total knee replacement

Submission date
01/05/2017

Recruitment status
No longer recruiting

Registration date
03/05/2017

Overall study status
Completed

Last Edited
08/06/2022

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Osteoarthritis is a condition that causes joints to become painful and stiff. Total knee replacement (TKR), which involves replacing the knee with an artificial joint, is the treatment of choice for patients suffering from long-standing severe pain, functional limitation and instability caused by osteoarthritis of the knee joint. Knee joint instability causes a feeling of 'unsteadiness' whilst walking and may also contribute to falls. In view of the latter, it is important for this issue of 'unsteadiness' to be addressed. TKR helps to remove the cause of pain and swelling, but exercises are crucial to counteract the joint's instability and any feeling of 'unsteadiness' before and after surgery. However, research hasn't yet found the best approach for delivering exercises to help with patients' rehabilitation. Current studies have tried to incorporate rehabilitation programmes to improve this issue, but required a delivery of 6-8 weeks of exercises which has resulted in a logistical burden due to the long duration. A new programme of exercise has been developed for the muscles of the knee that can be delivered during a single week before surgery. The pre-surgery exercise programme (P-SEC) potentially offers similar effectiveness for improving the feeling of 'unsteadiness' and muscle fitness as programmes that last much longer. Therefore, the aim of this study is to test the effectiveness of this new, short approach to exercising in patients who are waiting for TKR surgery.

Who can participate?
Patients over the age of 18 with severe osteoarthritis and awaiting TKR

What does the study involve?
Participants are randomly allocated into three groups. The first group carry out the exercise programme using the leg awaiting surgery. The second group carry out the exercise programme using the opposite leg. The third group do not carry out the exercise programme. During the exercise programme participants are asked to perform a set of 36 short exercises across three alternate days. The exercises are performed on a seated knee extensor machine. The participants are asked to lift the foot bar with both legs, lowering the allocated leg and catching the weight with that same leg. This movement is repeated at different weights across the three alternate days with appropriate recovery time in between each exercise. The participants' knees

are assessed at the start of the study, 2 weeks before surgery (before the exercise programme), 1 week before surgery (at the end of the exercise programme), on the day of surgery and 6 weeks after surgery.

What are the possible benefits and risks of participating?
The intensity and extent of the tests required for this study are no more than what patients would experience during normal rehabilitation sessions. In addition, the exercises proposed in this study are tailored to the participant's physical abilities and are pain free. Thus, the risks to patients taking part in this study are no more than those of normal clinical practice and daily activities. The assessments and exercises are carried out by a qualified, experienced physiotherapist who works with members of the medical team to ensure safety and care of the participant during the study.

Where is the study run from?
Robert Jones and Agnes Hunt Orthopaedic Hospital NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
March 2017 to May 2018

Who is funding the study?
Endeavour Scholarship Scheme Malta, European Social Funds 2020

Who is the main contact?
Ms Anna Maria Risso

Contact information

Type(s)
Scientific

Contact name
Ms Anna Maria Risso

Contact details
31/3 Arden Street
Edinburgh
United Kingdom
EH9 1BS

Additional identifiers

EudraCT/CTIS number

IRAS number
198930

ClinicalTrials.gov number
NCT03113032

Secondary identifying numbers

IRAS198930

Study information

Scientific Title
Novel Pre-Surgery Exercise-Conditioning (P-SEC) in patients waiting for a Total Knee Arthroplasty (TKA): a randomised controlled trial

Acronym
P-SEC

Study objectives
What is the efficacy of a pre-surgery exercise conditioning (P-SEC) programme for motor performance of the surgical leg in eliciting significant gains in functional, sensorimotor, neuromuscular and psychophysiological performance capabilities in patients awaiting TKA? The effectiveness of the P-SEC conditioning will be gauged against local contemporary practice (no conditioning), against relative gains in performance associated with P-SEC of the non-surgical leg and against perseverance of beneficial effects following TKA surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East Scotland Research Ethics Committee Local 01, 08/03/2017, ref: 17/SS/0005

Study design
Single-centre randomised 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 contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Patients with severe osteoarthritis of the knee awaiting a Total Knee Replacement (TKR)

Interventions
The patients will be block randomised into three groups by a member of the medical team at RJAH NHS Trust Foundation. The list of patients allocated to which group will be kept by the

same medical team member in a safe allocated area and will only be given to the chief investigator towards the end of the trial to allow for appropriate blinding.
1. Experimental group 1 will receive the P-SEC intervention on the leg awaiting surgery (surgical leg)
2. Experimental group 2 will receive the P-SEC intervention on the opposite leg (non-surgical leg)
3. Control group - no intervention will be applied to either of the patient's legs

The P-SEC intervention is an exercise-based intervention, where patients in the experimental groups, will be asked to perform a set of 36 short/brief exercises across 3 alternate days. The exercises are performed on a seated knee extensor machine. The patients will be asked to lift the foot bar (set at appropriate weight intensities according to the protocol) with both legs, lowering the experimental leg and catching the weight with that same leg. This movement is repeated at different weight intensities across the 3 alternate days with appropriate recovery time in between each exercise.

There are five data assessment points: baseline, 2-weeks prior to surgery (prior to the P-SEC intervention in the experimental groups), 1 week prior to surgery (at the end of the P-SEC intervention in the experimental groups), on the day of surgery and 6 weeks post-surgery.

Intervention Type
Behavioural

Primary outcome measure
Electromechanical Delay (EMD) of the knee extensor musculature. The data obtained will give an indication of the participants' sensorimotor and neuromuscular performance capacities. Measurements of the latter's activity will be obtained from electromechanical signals collected by a purpose-built dynamometer (Gleeson et al. 2013) and EMG signals obtained from surface electrodes over the knee extensor musculature.

Both the primary and secondary outcome measures will be taken at five data assessment points: baseline, 2-weeks prior to surgery (prior to the P-SEC intervention in the experimental groups), 1 week prior to surgery (at the end of the P-SEC intervention in the experimental groups), on the day of surgery and 6 weeks post-surgery.

Secondary outcome measures
1. Sensorimotor and neuromuscular performance capacities through balance force plate, peak force (PF), rate of force development (RFD) and H-Reflex using data obtained from the EMG and seated dynamometer used for the primary outcome measurement
2. Patients’ perceived performance capacities in function and pain, measured through various subjective questionnaires such as:
2.1. Knee Injury and Osteoarthritis Outcome Score (KOOS)
2.2. Oxford Knee Score (OKS)
2.3. Category-Ratio Scale (CR-10) Performance profile
2.4. SF-36v2
2.5. Pain Self Efficacy questionnaire
2.6. Physical activity questionnaire (IPAQ)

Both the primary and secondary outcome measures will be taken at five data assessment points: baseline, 2 weeks prior to surgery (prior to the P-SEC intervention in the experimental groups), 1 week prior to surgery (at the end of the P-SEC intervention in the experimental groups), on the day of surgery and 6 weeks post-surgery.

Overall study start date
22/03/2017

Completion date
06/04/2018

Eligibility

Key inclusion criteria
1. Males and females over the age of 18
2. Diagnosed with severe osteoarthritis (OA)
3. Awaiting primary TKA (Including contralateral knee OA/TKA and/or other orthopaedic conditions affecting the contralateral leg)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Total final enrolment
29

Key exclusion criteria
1. Individuals electing primary knee arthroplasty surgery due to a knee joint disease other than osteoarthritis - rheumatic disorder
2. Other orthopaedic conditions affecting lower body function
3. Neurological disorders
4. Individuals with reduced mental capacity affecting their ability to follow exercise programme

Date of first enrolment
15/05/2017

Date of final enrolment
23/01/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Robert Jones and Agnes Hunt Orthopaedic Hospital NHS Foundation Trust
Oswestry
United Kingdom
SY10 7AG

Sponsor information

Organisation
Queen Margaret University

Sponsor details
Queen Margaret University Drive
Musselburgh
Edinburgh
Scotland
United Kingdom
EH21 6UU

Sponsor type
University/education

Website
http://www.qmu.ac.uk

ROR
https://ror.org/002g3cb31

Organisation
Robert Jones and Agnes Hunt NHS Foundation Trust

Sponsor details
Gobowen
Oswestry
Gobowen
England
United Kingdom
SY10 7AG

Sponsor type
Hospital/treatment centre

Website
http://www.rjah.nhs.uk

Funder(s)

Funder type
Government

Funder Name
Endeavour Scholarship Scheme Malta, European Social Funds 2020

Results and Publications

Publication and dissemination plan
The results from the RCT will be published through appropriate scientific journals and presented at relevant conferences following analysis of the full dataset obtained at the end of the trial. The protocol of the trial will be published in scientific journals and presented at local and international conferences during the duration of the trial and following its completion.

2018 results in thesis https://core.ac.uk/display/222840839?source=3

Intention to publish date
27/09/2018

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current 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		07/06/2022	08/06/2022	Yes	No
HRA research summary			28/06/2023	No	No