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Effects of Maitland's Mobilization on modulating biomarkers in knee osteoarthritis

Submission date
29/04/2018

Recruitment status
No longer recruiting

Registration date
16/09/2019

Overall study status
Completed

Last Edited
07/02/2019

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Osteoarthritis is a common joint condition associated with changes in bone and synovial (joint) fluid and destruction of cartilage. However, the involvement of these processes in causing osteoarthritis is still not clear. Measurement of joint space width on plain x-rays is the most valid method of assessing osteoarthritis-related joint damage. The disadvantage of this method is the long gap required between two assessments to see whether the osteoarthritis has improved or deteriorated. Other methods include Magnetic Resonance Imaging (MRI), which is more sophisticated than plain x-ray yet not enough to measure changes in progression or cure of disease. Biochemical markers are another way to measure potential changes in the process of turnover. Biochemical markers are connective tissue molecules which release into the synovial fluid during cartilage or bone turnover. Some studies in animals and humans with osteoarthritis suggest that biochemical markers might be useful in detecting, identifying or measuring high-risk patients. The aims of this study are to compare the effects of Maitland's Mobilization with conventional treatment on pain, joint function, quality of life, and cartilage, bone and synovial biomarkers in knee osteoarthritis.

Who can participate?
Patients aged 50 to 70 with osteoarthritis

What does the study involve?
Participants are randomly allocated into two groups to be treated with either Maitland's Mobilization or conventional treatment. Maitland's Mobilization may vary slightly patient to patient; however, in general the treatment involves exercises three days a week on alternate days. Conventional treatment includes Electrical Heating Pads and Pulse Shortwave Diathermy applied for 15 minutes each, followed by exercises including knee isometrics, knee pressing, knee squeezing and mid-range straining leg raises. Participants are assessed at the end of every sixth week of treatment.

What are the possible benefits and risks of participating?
If successful, the treatment could decrease the severity of osteoarthritis and could be used as a preventative method for potential patients with degenerative joint disease. The study will provide information about changes in biochemical markers that occur with manual therapy

manoeuvres. If the findings suggest manual therapy manoeuvres can change biochemical markers, health care support such as drugs and nutrition could be used to change those biochemical markers. This could provide a new approach for a degenerative joint disease that is otherwise irreversible in nature. Degenerative joint disease is so far considered manageable but not curable.

Where is the study run from?
1. Riphah Rehabilitation Center (Pakistan)
2. Lahore General Hospital (Pakistan)
3. Ali Hospital (Pakistan)

When is the study starting and how long is it expected to run for?
July 2018 to December 2019

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Maryam Shabbir

Contact information

Type(s)
Public

Contact name
Dr Maryam Shabbir

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
isra/phd/maryam

Study information

Scientific Title
Effects of Maitland’s Mobilization on modulating biomarkers in knee osteoarthritis

Study objectives

NULL HYPOTHESIS (H0)
H0: There will be no significant outcomes of Maitland's Mobilization on modulating cartilage biomarkers (urine II collagen C-telopeptide, serum cartilage oligomeric matrix protein and serum YKL-40) in knee osteoarthritis
H0: There will be no significant outcomes Maitland's Mobilization on modulating bone biomarkers (Serum Total osteocalcin, urine types I and II collagen C-telopeptide, serum urine types I and II collagen C-telopeptide) in knee osteoarthritis
H0: There will be no significant outcomes Maitland's Mobilization on modulating synovial biomarkers (human cartilage glycoprotein, glucosyl-galactosyl pyridinoline, type III collagen N-propeptide, hyaluronic acid and C reactive protein) in knee osteoarthritis
H0: There will be no significant outcomes Maitland's Mobilization in reducing pain in knee osteoarthritis
H0: There will be no significant outcomes Maitland's Mobilization in improving joint function in knee osteoarthritis
H0: There will be no significant outcomes Maitland's Mobilization on quality of life in knee osteoarthritis

ALTERNATIVE HYPOTHESIS (H1)
H1: There will be significant outcomes of Maitland's Mobilization on modulating cartilage biomarkers (urine II collagen C-telopeptide, serum cartilage oligomeric matrix protein and serum YKL-40) in knee osteoarthritis
H1: There will be significant outcomes of Maitland's Mobilization on modulating bone biomarkers (Serum Total osteocalcin, urine types I and II collagen C-telopeptide, serum urine types I and II collagen C-telopeptide) in knee osteoarthritis
H1: There will be significant outcomes of Maitland's Mobilization on modulating synovial biomarkers (human cartilage glycoprotein, glucosyl-galactosyl pyridinoline, type III collagen N-propeptide, hyaluronic acid and C reactive protein) in knee osteoarthritis
H1: There will be significant outcomes of Maitland's Mobilization in reducing pain in knee osteoarthritis
H1: There will be significant outcomes of Maitland's Mobilization in improving joint function in knee osteoarthritis
H1: There will be significant outcomes of Maitland's Mobilization on quality of life in knee osteoarthritis

Ethics approval required

Old ethics approval format

Ethics approval(s)

Research Ethical Committee, Institutional Review Board and Board of Advanced Studies and Research in Isra University, 26/03/2018

Study design

Randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)
Other

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
Knee osteoarthritis

Interventions
Patients will be randomly allocated into two groups by coin tossing method i.e. Maitland's Mobilization and Conventional Group.

Maitland's Mobilization
Protocol may vary slightly patient to patient; however, general treatment protocol is being applied as follows:
1. Frequency of exercise is three days a week on alternative day basis
2. Intensity is Grade I and II based on Maitland concept
3. Intensity is progressed to Grade III of Maitland's Grading System, in case, in order to achieve restore, compensate or prevent stiffness and flexibility issues
4. Time of oscillations are 2 or 3 oscillations in a second for 1 to 2 minutes
Patient Position
Patient lies supine on treatment table with affected knee towards clinician standing side. The knee should be in a resting position of 250. A wedge roll sometimes is used to maintain position or support below knee.
Patient Education
Patient is educated regarding the procedure. Precautions of pain provocation are briefed to the patient.
Therapist/Clinician Position
The therapist is in a standing position, facing towards patient on side of patient's leg under treatment. The therapist holding to fix femur at its distal end while the tibia being oscillated with other hand as per protocol mentioned above.

Conventional Treatment
This includes Ottawa Panel Evidence-Based Clinical Practice Guidelines for Therapeutic Exercises, after essential modifications to fit in Pakistan's framework of practice. The hallmark of treatment is covering pain and daily function. Electrophysiological agents and muscle stabilization are used.
Electrical Heating Pads and Pulse Shortwave Diathermy is applied for 15 minutes each, followed by exercises including knee isometrics, knee pressing, knee squeezing and mid-range straining leg raises. Transcutaneous electrical nerve stimulator should be given for 10-15 additional minutes.

A range of assays/kits will be used for identifying and measurement of various types of biomarkers. The ELISA method will be used in the lab of Riphah College of Rehabilitation Sciences. Lahore Campus. Personnel from the biochemistry department will assist with this procedure and process.

After completing the initial screening process, every requited patient will be assessed by an independent assessor expert using primary and secondary outcome measurement tools. This will be included in the baseline assessment. Onwards at end of every sixth week of treatment, every patient will undergo the assessment process. Follow-up examination to be done while patients are advised for Home Plan Exercises after 18 weeks. Follow up to be at 24th week.

Intervention Type
Other

Primary outcome measure
Measured at baseline and every sixth week of treatment:
1. Biomarkers of osteoarthritis measured using ELISA
2. Function, range and pain experienced due to osteoarthritis measured using the Western Ontario and McMaster Universities Arthritis Index (WOMAC)

Secondary outcome measures
Measured at baseline and every sixth week of treatment:
1. Pain intensity measured using the Numeric Rating Pain Scale
2. Quality of life and problems specific to knee region measured using the Knee Injury and Osteoarthritis Outcome Score (KOOS)
3. General quality of life measured using the SF 36 Short Form

Overall study start date
02/07/2018

Completion date
02/12/2019

Eligibility

Key inclusion criteria
1. Patients of either gender
2. Age 50 to 70 years
3. Patients falling in American College of Rheumatology criteria for primary osteoarthritis
4. Patients with chronic pain from last three months
5. Kellgren-Lawrence Classification System for knee osteoarthritis
6. Patients with body mass index not below than 19 kg/m2 and more than 28 kg/m2
7. Patients who have signed informed consent to be willing to participate in study

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
68

Key exclusion criteria
1. Patients with trauma in last 6 months
2. Patients with uncontrolled diabetes mellitus and hypertensive disease
3. Associated inflammatory joint disease such as septic arthritis and R.A
4. Patients taking cover of oral or intra-articular Hyaluronic acid
5. Patient on cover of alendronate and/ or sulfonate compounds of sodium
6. Women receiving any treatment that can interfere with bone metabolism such as hormonal replacement therapy after menopause
7. Patients with undiagnosed pathology or impairment, recent surgery, mixed arthritis condition, patients with spinal problems

Date of first enrolment
02/07/2018

Date of final enrolment
01/04/2019

Locations

Countries of recruitment
Pakistan

Study participating centre
Riphah Rehabilitation Center
14 Civic Center, Township
Lahore
Pakistan
54000

Study participating centre
Lahore General Hospital
Ferozpur Road
Lahore
Pakistan
54000

Study participating centre
Ali Hospital
Shalimar Link Road
Lahore
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Sponsor information

Organisation
Higher Education Commission

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Sponsor type
Government

Organisation
Riphah International University

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Sponsor type
University/education

Organisation
Higher Education Commission

Sponsor details

Sponsor type
Government

Website
http://www.hec.gov.pk/

ROR
https://ror.org/038y3sz68

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
1. A systematic review in process regarding its previous literature
2. Cross cultural adaptation and translation of outcome measures in also in process that will be published and disseminated during this study

Email: physiomalik1@gmail.com; maryambutt85@hotmail.com The measures will be taken into account regarding maintaining confidentiality and privacy of patients in study. The data will be placed in secure and locked place. Data will be discarded after 3 years or before after dissemination and publication of all components of study.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request