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Comparing three management methods for knee osteoarthritis

Submission date
08/04/2019

Recruitment status
No longer recruiting

Registration date
22/04/2019

Overall study status
Completed

Last Edited
10/12/2019

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 (OA) is the commonest joint disorder that can cause pain, disability and affects the quality of life. There is conflicting evidence regarding the best management method for OA. The aim of this study is to assess the effect of PRP and hyaluronic acid intra articular knee injections on pain, function and quality of life, and to compare between them and a conventional physiotherapy program.

Who can participate?
Patients with chronic (at least 4 months) knee pain and x-ray evidence of OA

What does the study involve?
Participants are randomly allocated to one of the three groups. Detailed physical examinations are performed and an evaluation form is completed. Demographic features including age, occupation and level of education are recorded for each participant. Routine lab tests and blood tests are performed. Group I receive two PRP knee injections with a one-month interval. Group II receive four weekly knee injections of sodium hyaluronate. Group III receive 12 one-hour sessions (three per week) of a specialized exercise program supervised by a physiotherapist. All participants receive a home rehabilitation program and educational leaflet. All participants are evaluated initially, then after 2 and 6 months after treatment completion.

What are the possible benefits and risks of participating?
Participation may benefit future patients by showing the effectiveness of these treatments. Participation in this study is not expected to cause any risks greater than those encountered in everyday life, as these treatments are already currently used in daily practice for treating OA.

Where is the study run from?
Dubai and Rashid Hospitals (United Arab Emirates)

When is the study starting and how long is it expected to run for?
February 2016 to December 2018

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers
DSREC-12/2015-2016

Study information

Scientific Title
Platelet rich plasma versus hyaluronic acid injections and conventional physical therapy in management of knee osteoarthritis

Study objectives
Platelet rich plasma and hyaluronic acid injections are more effective than conventional physical therapy in management of knee osteoarthritis

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/03/2016, Dubai scientific research ethical committee (DSREC) (Rashid Medical Library, Medical Education & Research Department, Dubai, UAE, P.O. 4545; Tel: +971 (0)4 219 1961; Email: DSREC@dha.gov.ae), ref: DSREC-12/2015-2016

Study design
Interventional single-blinded computer-generated random allocation multi-center study

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format however contacting the author on email: sskhalil@dha.gov.ae, it can be sent upon request

Health condition(s) or problem(s) studied
Chronic knee pain associated with imaging findings of mild to moderate degenerative changes in the knee joint

Interventions
Randomization was performed using a computer-generated program. The enrolled patients were randomly distributed into three groups:

Group I included 20 patients who received two PRP intraarticular knee injections under ultrasound guidance. PRP was prepared using (Dr. PRP Kit [Rmedica, Seoul, Republic of Korea]) by the following method: 18 millilitres of the patient's blood was collected and mixed with 2mL ethylene di-amine tetra-acetic acid disodium anticoagulant (EDTA; Wako Pure Chemical Industries, Ltd.). Then, it was placed in a centrifuge first spin at a force of 3,000 RPM for 3 minutes to separate erythrocytes from the plasma. After that, the obtained plasma was centrifuged again for a second spin at a force of 3,200 RPM for another 6 minutes to separate the platelet poor plasma (PPP) from the platelet-rich plasma (PRP). PRP injections were given with a one-month interval.

Group II included 20 patients who received four weekly intraarticular knee injections of sodium hyaluronate 20 mg/2 mL (Hyalgan®, Fidia S.p.A, Abano Terme, Italy) under ultrasound guidance. Hyalgan is a viscous solution consisting of a high molecular weight (500,000–730,000 Da) fraction of purified natural sodium hyaluronate in buffered physiological sodium chloride, having a PH of 6.8–7.5. The sodium hyaluronate is extracted from rooster combs.

Group III included 20 patients who received 12 sessions (three per week), each last for one hour of a specialized exercise program supervised by the physiotherapist. They were asked to do their daily knee resistance and flexibility exercises in three sets of 10 repetitions and one set of five repetitions, respectively.

N.B: all patients of the three groups will receive a home rehabilitation program and educational leaflet

All patients were evaluated initially, then after 2 and 6 months after therapy completion. An independent physician who was blinded to patients' group allocation throughout the study performed all evaluations. The subjects filled a questionnaire about their demographic data and medical history. They were evaluated by detailed physical examination, imaging techniques, grey-scale musculoskeletal ultrasound (MSUS) knee examination, and laboratory tests including complete blood count (CBC) to screen for inclusion and exclusion criteria.

The total duration of the trial is 7 months for each patient (1 month for therapeutic intervention and 6 months follow-up).

Intervention Type
Mixed

Primary outcome measure
Pain severity measured using Visual Analogue Scale (VAS) of shoulder pain initially, then after 2 and 6 months of therapy. Patients point to their amount of pain on a scale of zero (no pain) to 100 (agonizing severe pain), according to their subjective feelings on a 100-millimeter scale drawn on paper. In this scale, a higher score indicates much pain.

Secondary outcome measures
Measured initially, then after 2 and 6 months of therapy:
1. Physical knee examination: limitation in knee range of motion (ROM) and assessment of the presence of effusion
2. Western Ontario and McMaster Universities Arthritis Index (WOMAC): WOMAC comprises 24 multiple-choice items. Each item is scored using a 5-point scale (with 1 point indicating the best function and 5 points, the worst): aggregate scores for joint-specific pain (5 items), physical function (17 items), and stiffness (2 items) are calculated. Use of an overall score is not

recommended.
3. Health-related quality of life measured by RAND 36-Item Short-Form Health Survey (SF-36): 36-Item SF-36 is a self-administered 36-item questionnaire comprising 8 health dimensions: physical function (PF), bodily pain (BP), role limitations related to physical health (PR), general health (GH), mental health (MH), role limitations related to emotional health (ER), vitality (VT) and social functioning (SF). Scoring for the eight dimensions ranges from 0 to 100 points, with higher scores indicating better health.
4. NSAIDs consumption: number of days over the past week the patient had consumed NSAID tablets
5. Patient satisfaction registered by means of five-point Likert Scale (not at all satisfied; slightly satisfied; somewhat satisfied; very satisfied; extremely satisfied)

Overall study start date
03/02/2016

Completion date
30/12/2018

Eligibility

Key inclusion criteria
1. History of chronic (at least 4 months) pain or swelling of the knee
2. Imaging findings (radiography) of mild to moderate degenerative changes in the knee joint on Kellgren–Lawrence scale from I–III

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
60 patients

Key exclusion criteria
1. Age >80 years
2. Rheumatic pathologies (rheumatoid, psoriatic and reactive arthritis, and seronegative spondyloarthritis)
3. Hematological diseases (coagulopathies)
4. Severe systemic diseases (renal, hepatic, cardiac, infections, endocrinopathies, malignancies)
5. Patients on therapy with anticoagulants–anti-aggregants
6. Use of NSAIDs within 5 days before blood procedure
7. Grade IV gonarthrosis
8. History of knee operarion, or recent knee trauma
9. Previous intra-articular injection with steroids, HA and/or PRP
10. Hb values<11 g/dl, and/or platelet values<150.000/mm3

Date of first enrolment
20/03/2016

Date of final enrolment
19/03/2017

Locations

Countries of recruitment
United Arab Emirates

Study participating centre
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https://ror.org/01dcrt245

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
The results will be published as soon as they are ready.

Intention to publish date
31/01/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a repository.

IPD sharing plan summary
Stored in repository