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Intra-articular platelet-rich plasma vs corticosteroids in the treatment of moderate knee osteoarthritis

Submission date
30/08/2019

Recruitment status
No longer recruiting

Registration date
16/09/2019

Overall study status
Completed

Last Edited
13/07/2020

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Osteoarthritis (OA) is a condition that causes joints to become painful and stiff that results from the breakdown of joint cartilage and underlying bone. Platelet-rich plasma (PRP) injections bathe troubled cells in a concentrated mixture of platelets from patients own blood. Although it is not exactly clear how PRP works, laboratory studies have shown that it can potentially speed up the healing process in some injuries. Triamcinolone acetonide is a synthetic corticosteroid used topically to treat various skin conditions, to relieve the discomfort of mouth sores, and intra-articularly (in the joints) to treat various joint conditions. The aim of this study was to compare intra-articular injections of autologous PRP with intra-articular injections of corticosteroid to relieve the pain caused by OA.

Who can participate?
Patients older than 55 years with a history of chronic pain, swelling and/or reduced range of motion in the knee joint, confirmed to be OA.

What does the study involve?
Patients who met inclusion criteria were divided into two groups by random selection. Patients randomized to group 1 (platelet-rich plasma - PRP) received one intra-articular injection of autologous PRP. Patients randomized to group 2 (corticosteroid - CS) received an intra-articular injection of triamcinolone acetonide.

What are the possible benefits and risks of participating?
Patients may experience an improvement or no improvement in symptoms.

Where is the study run from?
ORTO Klinika LTD, Latvia

When is the study starting and how long is it expected to run for?
April 2016 to May 2017

Who is funding the study?
ORTO KLĪNIKA, Latvia

Who is the main contact?
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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
GO-CS

Study information

Scientific Title
Intra-articular platelet-rich plasma vs corticosteroids in the treatment of moderate knee osteoarthritis: a single-center prospective randomized controlled study with a one-year follow up

Acronym
PRP

Study objectives
We hypothesized that intraarticular injection of PRP reduces pain in a very-short term follow up (one week) similar to triamcinolone acetonide and leads to an equal or more effective analgesic and lasting functional recovery (one year)

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 10/02/2016, Rigas Stradins University (RSU) Êtikas Komitejas (Prof Olafs Brüvers, Riga, Dzirciema 16, LV-1007, Latvia; +37167409101), ref: E-9(2)
2. Approved 15/04/2016, Rīgas Austrumu klīniskās universitātes slimnīcas atbalsta fonda Medicīnisko un biomedicīnisko pētījumu ētikas komiteja (Rīga, Hipokrāta iela 2, LV1038, Latvia; +37 20281174; etika@aslimnica.lv), ref: 57/2016

Study design
Single-centre prospective randomized controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Knee osteoarthritis

Interventions
Patients suffering knee pain were redirected to the one physician of the clinical team involved in the trial who evaluated suitability.

Patients who met inclusion criteria were divided into two groups of 20 patients each by random selection. Patients randomized to group 1 (platelet-rich plasma - PRP) received one intra-articular injection of autologous PRP. Patients randomized to group 2 (corticosteroid - CS) received an intra-articular injection of corticosteroid. The randomization of patients was done using a randomization software list.

Pain VAS score at 1 year (change from baseline - V1) was considered the primary outcome variable. Secondary outcomes were International Knee Documentation Committee (IKDC 2000 form) scale and Knee Society Score (KSS) at any time point from: one week (V2), 5 weeks (V3), 15 weeks (V4) and 30 weeks (V5). VAS scores at short-term (1 week) was considered a secondary outcome.

The first assessment was performed at 1 week after the infiltration (V1) to evaluate if PRP clinical improvement was similar or superior to corticosteroid. Patients in the corticosteroid group received intraarticular 1 mL of 40 mg/mL of triamcinolone acetonide (Kenalog®) and 5 mL of 2 % of lidocaine, which was mixed in one syringe. A complete evacuation of intra-articular

fluid, if present, was performed before PRP and CS were injected intraarticular. The injecting physician neither the patient was blinded to treatment. All the baseline and follow-up visits were performed by the blinded evaluator who was blinded to the treatment throughout the study. The intra-articular knee injection was performed under sterile conditions without any local or general anesthesia with a 20-G x 2.75 70 mm needle using an anterolateral approach. Echographic control (Philips Affinity 70) allowed a proper needle position by direct visualization of the liquid PRP/CS injected. After manipulation aseptic bandage was used with local cool compression for 15 minutes. Nonsteroidal anti-inflammatory drugs were prohibited for 10 days following the injection.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
Platelet-rich plasma, triamcinolone acetonide - Kenalog®

Primary outcome measure
Pain VAS score at 1 year (change from baseline)

Secondary outcome measures
1. International Knee Documentation Committee (IKDC 2000 form) scale and Knee Society Score (KSS) at any time point: one week (V2), 5 weeks (V3), 15 weeks (V4) and 30 weeks (V5).
2. VAS scores at short-term (1 week)

Overall study start date
01/11/2015

Completion date
30/05/2017

Eligibility

Key inclusion criteria
1. Patients older than 55 years with a history of chronic pain, swelling and/or reduced range of motion in the knee joint
2. Clinical and radiological confirmation of OA of the knee (Kellgren – Lawrence KL grades II-III) was verified by assessing X-Ray images in anteroposterior and lateral projections

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
40

Total final enrolment
40

Key exclusion criteria
1. Posttraumatic knee
2. Pregnancy, breastfeeding
3. Oncological diseases
4. Endocrine diseases (gout, diabetes)
5. Autoimmune diseases (rheumatoid arthritis)
6. Acute/chronic infectious disease, blood clotting disorders (thrombocytopenia, coagulopathy)
7. Previous interventions on the knee joint (i.e. punctures, blockades, arthroscopy)
8. Received consistent hormonal therapy or non-steroidal anti-inflammatory drugs (NSAIDs) within 10 days prior to the intervention

Date of first enrolment
01/04/2016

Date of final enrolment
30/05/2017

Locations

Countries of recruitment
Latvia

Study participating centre
ORTO Klinika LTD
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Sponsor information

Organisation
ORTO KLĪNIKA

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Sponsor type
Hospital/treatment centre

Website
https://orto.lv/en

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
ORTO KLĪNIKA

Results and Publications

Publication and dissemination plan
Results will be published in Journal of Orthopaedic Surgery and Research

Intention to publish date
30/09/2019

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	results	10/07/2020	13/07/2020	Yes	No