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Does injection of an extract of a patient's own blood into a knee joint reduce inflammation caused by osteoarthritis?

Submission date
14/11/2019

Recruitment status
No longer recruiting

Registration date
23/01/2020

Overall study status
Completed

Last Edited
24/01/2020

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 thought to be caused by mechanical damage to the tissues of the joints that results in breakdown of the cartilage layer that protects the ends of the bones and inflammation within the joint. This causes pain, swelling, stiffness and loss of mobility. Serum is the fluid left after blood has clotted. It contains proteins that are thought to reduce inflammation and encourage healing. This study aims to investigate whether injecting serum prepared from a person's own blood into their knee joint can reduce pain and improve mobility in knees affected by osteoarthritis.

Who can participate?
Adults aged 18 - 55 years who have mild osteoarthritis of the knee that is causing pain.

What does the study involve?
Participants will have samples of the fluid in their joint taken using a needle, one week before the start of treatment, before each of the two serum treatments and six months after treatment. These samples will be tested for levels of substances involved in inflammation. They will have two injections of the serum one week apart. The preparation of the serum will involve blood being taken. They will be asked about their pain, mobility and the impact of their knee problems at the pre-treatment visits, the two treatment visits and six months after treatment at the follow-up visit.

What are the possible benefits and risks of participating?
The treatment is free of charge. All participants will receive the treatment. Participants might benefit from a reduction in inflammation and pain.
The serum is prepared from the participant's own blood in a sterile and enclosed system, which means there is no risk of infection or immune reactions. As with any procedure involving injections, there may be some discomfort, pain or redness. There is a small risk of inflammation or infection around the injection site. The post-injection discomfort is expected to cease within three to four days.

Where is the study run from?
OrthoSera (Hungary). This is the company that makes the device used to prepare the serum.

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

Who is funding the study?
OrthoSera (Hungary)

Who is the main contact?
Dr Eszter Fodor, eszterfodormd@gmail.com

Contact information

Type(s)
Scientific

Contact name
Dr Eszter Fodor

ORCID ID
https://orcid.org/0000-0002-9487-2824

Contact details
Kikelet utca 35/C
Budapest
Hungary
1125
+36306640494
eszterfodormd@gmail.com

Additional identifiers

Protocol serial number
20160201

Study information

Scientific Title
Evaluation of the synovial fluid inflammatory markers in the use of serum fraction of autologous platelet-rich fibrin, hyaluronic acid and their combination in the arthrosis of the knee joint

Acronym
ASPRF2016

Study objectives
1. Intraarticular injection of hyperacute serum decreases the concentration of inflammatory cytokines and matrix metalloproteinases presented in the osteoarthritic synovial fluid
2. Hyperacute serum injection has a beneficial effect on the level of pain and mobility of osteoarthritic patients

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/07/2016, Scientific and Research Ethics Committee of the Hungarian Health Science Council (051 Budapest, Arany J. u. 6-8; +361476 1100; igazgatas@oth.antsz.hu), ref: 6906 /2017/EKU

Primary study design
Interventional

Study design
Single-centre open-label randomized study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Osteoarthritis

Interventions
Before treatment, samples of synovial fluid are taken from the patient's affected knee and levels of 40 proteins are measured. This can be done if there is at least 1 ml of synovial fluid in the joint. The orthopedic surgeon extracts the fluid from the joint using a needle.
All participants receive injections of autologous hyperacute serum produced using OrthoSera's device at 1 and 2 weeks after the synovial fluid sampling. 18 ml of blood (without anticoagulant) is taken from the right or left forearm vein of the patient using a butterfly needle set into the hypACT Inject Auto medical device. The SPRF fraction (hyperacute serum) is isolated using this device in a closed system by centrifugation. After centrifugation, the serum can be refrigerated and injected to the patient's knee up to a week later or it can be injected immediately. It is transferred into a standard 5 ml syringe ready for injection into the affected knee joint.

Pain, mobility and the patient's opinion of their knee problems are assessed at baseline, after treatment at weeks 1 and 2, and at 6 months follow-up. Additional synovial fluid samples are taken at weeks 1 or 2 and at 6 months.

Intervention Type
Biological/Vaccine

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Autologous hyperacute serum

Primary outcome(s)
Markers of inflammation in synovial fluid measured using multiplex protein array (Luminex) technology at baseline, weeks 1 and 2, and month 6

Key secondary outcome(s)

1. Knee joint pain assessed using a Visual Analogue Scale (VAS) at baseline, week 1, week 2, and month 6
2. Knee joint mobility assessed using the Lysholm scale at baseline, week 1, week 2, and month 6
3. Patient's assessment of the impact of their knee impairment assessed using the Knee Injury and Osteoarthritis Outcome Score (KOOS) at baseline, week 1, week 2, and month 6

Completion date
01/04/2018

Eligibility

Key inclusion criteria
1. Early or mild arthrosis of the knee joint that complies with Kellgren-Lawrence Grade 2 or 3 on standing anteroposterior (AP) weight-bearing X-ray during the last 3 months before the enrolment. If the patient does not have a proper X-ray from the last 3 months and indicates that he/she intends to participate in the study, a current X-ray is taken and the diagnosis is made by an orthopaedic surgeon or a radiologist.
2. Aged 18 - 55 years
3. Pain indicated by the patient is at least 40 on a 0 to 100 VAS scale during the last 3 months before the enrolment and the pain is related to the arthrosis
4. Clinical assessment that the pain is caused by the arthrosis
5. Inflammatory arthropathy is not included in the medical history or it is not suspected during the assessment
6. If the patient has a liver or kidney failure, then stable condition within the last 6 months should be confirmed

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
27

Key exclusion criteria
1. Obesity (BMI >40 kg/m²)
2. Poorly controlled diabetes (HbA1C >7.5 or fasting glucose >11.11 mmol/l in the last 6 months
3. Surgery or injury of the other knee within 6 months or corticosteroid injection within 3 months
4. Inflammatory arthropathy in the medical history (e.g. rheumatoid arthritis, systemic lupus erythematosus involving the knee joint)

5. Diagnosis of any kind of rheumatoid arthritis or gout
6. Acute infection of the involved joint or in the surroundings, or untreated active infection or inflammation in any location
7. Moderate or severe anaemia (haemoglobin <11 g/dl) or thrombocytopenia (platelets <100,000 /µl), conditions with haemoglobin >17 g/dl or <11 g/dl and/or platelets >500,000/µl or <100,000 /µl
8. Dialysis or liver failure, or untreated kidney or liver failure. Patients with chronic liver or kidney failure may be enrolled if they can demonstrate that their disease has been stabilized in the last 6 months
9. Patients receiving therapeutic dose of anticoagulants (e.g. warfarin, dabigatran, enoxaparin) or patients with coagulopathy in their medical history should be excluded. Patients receiving platelet aggregation inhibitors (e.g. aspirin, clopidogrel) should not be excluded, in accordance with the clinical practice
10. Pregnant or breastfeeding. A pregnancy test with negative result should be performed on female patients with childbearing potential and they should declare that they are not breast-feeding
11. Alcohol or drug abuse
12. Uncontrolled psychiatric disorder
13. Lack of travel options (e.g. to the follow-up examinations and back) or cooperation during the visits/participation in all visits
14. Progressive or acute malignant disease
15. Haematopoietic diseases (e.g. sickle cell anaemia)
16. Population at risk: patients unable to make decisions independently about signing up for the trial, or those under external influence

Date of first enrolment
01/09/2016

Date of final enrolment
01/01/2017

Locations

Countries of recruitment
Hungary

Study participating centre
Kastélypark Klinika [Castle Park Clinic]
Hajdú street. 17
Tata
Hungary
2890

Sponsor information

Organisation

OrthoSera Kft.

Funder(s)

Funder type
Industry

Funder Name
OrthoSera Kft.

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date