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Osteoarthritis stem cell therapy

Submission date
14/02/2017

Recruitment status
No longer recruiting

Registration date
24/02/2017

Overall study status
Completed

Last Edited
23/10/2020

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 the most common type of arthritis and is a main cause of disability and pain. It occurs when the protective cartilage on the end of bones wears away. The bones then rub against one another, causing stiffness, pain and a reduction in the range of movement. The treatment for OA mostly focuses on helping relieve the pain and control symptoms instead of solving the problem. Recently there have been new ideas and technology in orthopedic surgery (surgery that corrects bones and muscles) that has come up with alternative treatments. Using adipose tissues (fat cells) from a patient could help repair the bones and cartilage if it is injected into the area affected with OA. The new Lipogems® technology is a closed system that is designed to harvest, process and inject adipose tissues back into patients to help repair the area with OA. The aim of this study is to evaluate the outcomes of treating patients with knee osteoarthritis and cartilage lesions with adipose tissue to see if it helped improve the knee's function and reduce pain.

Who can participate?
Patients aged 40-85 years old with knee osteoarthritis.

What does the study involve?
Participants undergo a physical examination and complete a health questionnaire. They then undergo a surgical procedure using the Lipogems system® which takes fat tissues from the patient's stomach area and then reinjects the fat tissues into the knees. Participants have a blood sample collected during the procedure and as well in the follow up at six and 12 months. They are followed up at three, six and 12 months after procedure to assess the pain level and the function the knee.

What are the possible benefits and risks of participating?
A potential benefit for patients is pain reduction and functional improvement of the affected knee. The main risks are haematoma (swelling) at area where the adipose tissue is taken from and short-term knee pain after the procedure. Participants may feel discomfort during the blood test.

Where is the study run from?
1. Specialty Hospital St. Catherine (Croatia)
2. Genos Ltd. laboratory (Croatia)

When is the study starting and how long is it expected to run for?
September 2015 to January 2018

Who is funding the study?
Specialty Hospital St. Catherine and Genos Ltd. Laboratory (Croatia)

Who is the main contact?
Dr. Andrea Skelin

Contact information

Type(s)
Scientific

Contact name
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Contact details
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Bračak 8
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49210

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
EP 001/2016

Study information

Scientific Title
Application of adipose derived mesenchymal stem cells (Ad-MSC) in treating OSTeoarticular and Cartilage lesions

Acronym
OSCT

Study objectives
The aim of this study is to explore trophic, mitogenic, anti-scarring, anti-apoptotic, immunomodulatory, and anti-microbial clinical effects of autologous adipose-derived stromal /stem cells (Ad-MSC) in treating patients with osteoarticular and cartilage lesions.

Ethics approval required

Old ethics approval format

Ethics approval(s)
St. Catherine Hospital Ethic Committee, 18/1/2016, ref: EP 001/2016

Study design
Non randomised study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format

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

Interventions
Participants undergo a complete physical examination including X-rays/MRI and biochemical laboratory tests. Participants also complete a specific questionnaire (International Knee Documentation Committee (IKDC)) to assess their health.

Participants then undergo a surgical procedure (lipoaspiration). The Lipogems® technology, patented in 2010 (PCT/IB2011/052204), is a completely closed tool to harvest, wash, process, and reinject human (or animal) lipoaspirates. This surgical procedure consists of two steps: the infiltration step, in which adrenaline, in a saline solution, and very diluted lidocaine are injected to induce vasoconstriction as well as local anesthesia is injected to facilitate the subsequent lipoaspiration and the aspiration step, in which a standard liposuction technique is performed. The tissue is taken from the abdominal subcutaneous adipose tissue.

They then receive intra-articular injection of final product containing derivate of micronized fatty tissue and intact vascular/stromal architecture with pericytes and mesenchymal stem cells (Ad-MSC) into affected knee (or knees)

Participants have plasma blood collection and synovial fluid aspirates of IgG glycom analyses taken during the procedure and 6 and 12 months.

Followed up is done at baseline, 3, 6 and 12 months to measure the pain level and the functioning of the knee (or knees). In addition MRI and dGEMRIC MRI imaging are performed at baseline and at 3, 6 and 12 months.

Intervention Type

Device

Primary outcome measure
1. Pain in the knee is measured using the visual analogue scale (VAS) at the baseline, 3, 6 and 12 months
2. Function of the knee is measured using Knee Injury and Osteoarthritis Outcome Score (KOOS) at baseline, 3, 6 and 12 months

Secondary outcome measures
1. Matrix synthesis in the cartilage layer (glycosaminoglycan content) delayed gadolinium enhanced MRI (dGEMRIC) imaging technique is applied at the baseline, 3, 6 and 12 months.
2. Changes in IgG glycosylation associated with inflammatory processes analyses of IgG glycom from the blood plasma and synovial fluid (when available) is performed at baseline, 6 and 12 months
3. Subchondral bone edema, morphology of cartilage and soft tissues is measured by MRI scans at baseline and at 3, 6 and 12 months

Overall study start date
14/09/2015

Completion date
18/01/2018

Eligibility

Key inclusion criteria
1. Age 40-85
2. Knee osteoarthritis (radiological Kellgren and Lawrence grade II-IV)
3. Onset of symptoms for more than 6 months in the painful knee
4. Able to follow the instructions of the study
5. Signed an informed consent form

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
30

Total final enrolment
32

Key exclusion criteria
1. Age less than 40 years or more than 85 years
2. Chondromatosis or villonodular synovitis of the knee

3. Recent trauma (<3 month) of the symptomatic knee
4. Infectious joint disease
5. Malignancy
6. Patients on anticoagulant therapy with PT (< 0,70) or suffering from thrombocytopenia and /or coagulation disorder
7. Hypersensitivity to local anaesthetic

Date of first enrolment
18/01/2016

Date of final enrolment
16/06/2017

Locations

Countries of recruitment
Croatia

Study participating centre
Specialty Hospital St. Catherine
Bračak 8
Zabok
Croatia
49210

Study participating centre
Genos Ltd. Laboratory
Hondlova 2/11
Zagreb
Croatia
10000

Sponsor information

Organisation
Specialty Hospital St. Catherine

Sponsor details
Bračak 8
Zabok
Croatia
49210

Sponsor type
Hospital/treatment centre

Website
http://en.svkatarina.hr

Organisation
Genos Ltd. Laboratory

Sponsor details
Hondlova 2/11
Zagreb
Croatia
10000

Sponsor type
Research organisation

Website
http://genos.hr/en/

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Specialty Hospital St. Catherine

Funder Name
Genos Ltd

Results and Publications

Publication and dissemination plan
The first preliminary data we are planning to present at the 10th International Society for Applied Biological Sciences (ISABS) Conference to be held in June 2017. Planned publication in a high-impact peer reviewed journal in 2019.

Intention to publish date
31/01/2019

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study 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	13/10/2017	22/10/2020	Yes	No
Other publications	sub study	21/06/2019	23/10/2020	Yes	No
Results article	24 month follow up results	17/12/2019	23/10/2020	Yes	No
Results article	results	13/06/2019	23/10/2020	Yes	No