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Evaluation of quality of life following treatment with Hymovis in patients with knee osteoarthritis and/or meniscal tear

Submission date
26/04/2023

Recruitment status
No longer recruiting

Registration date
11/05/2023

Overall study status
Completed

Last Edited
11/05/2023

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 most common joint disease in the world population. It is characterized by cartilage degeneration and knee pain and dysfunction. A meniscus tear is an injury to a part of the knee called the meniscus. The menisci are two crescent-shaped pads of thick, rubbery shock-absorbing cartilage in the knee joint. They lie between the thigh bone (femur) and the shin bone (tibia). Knee OA and meniscus tears are among the most common knee injuries. There are several oral treatments available with proven effectiveness for this disease. Hyaluronic acid (HA) offers a new alternative treatment. The aim of this study is to evaluate treatment with a special type of HA commercialized under the name Hymovis.

Who can participate?
Patients aged 18 years and over with knee OA or meniscus tear who come for medical examination after an injection of Hymovis

What does the study involve?
Information is collected for 3 months for patients with meniscal tear and 6 months for patients with knee OA. At the inclusion visit (10 days after the last injection of Hymovis) the pain and functionality of the knee that the patients had before undergoing the treatment is evaluated. Follow-up visits are after 1, 2 and 3 months for the meniscal tear group and after 1, 2, 3, and 6 months for the knee OA and mixed group.

What are the possible benefits and risks of participating?
The patients will participate in an innovative study. There are no risks expected.

Where is the study run from?
Centre de Tecnificació Esportiva de la Residencia Blume (Spain)

When is the study starting and how long is it expected to run for?
July 2018 to December 2020

Who is funding the study?
MSK Diagnòstic i Docència SLP (Spain)

Who is the main contact?
Dr Ramón Balius Matas, ramonbaliusmatas@gmail.com

Contact information

Type(s)
Principal investigator

Contact name
Dr Ramon Balius Matas

Contact details
Centre de Tecnificació Esportiva de la Residencia Blume.
onsell Català de l'Esport
Generalitat de Catalunya
Av. dels Països Catalans, 40-48
Esplugues de Llobregat
Barcelona
Spain
08950
+34 (0)628305581
ramonbaliusmatas@gmail.com

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
BAL-HYA-2018-01

Study information

Scientific Title
Quality of life, physical activity and satisfaction of patients after intra-articular injection of hyaluronic acid with mobile reticulum for the treatment of chondral injury of the knee due to osteoarthritis due to overuse and/or in the conservative treatment of the meniscus injury

Acronym
HYAQoL

Study objectives
The main objective of this study is to evaluate the improvement in quality of life, through the assessment, among other things, of the return to physical activity and patient satisfaction after

intra-articular injection of hyaluronic acid with mobile reticulum (viscosupplementation) in knee injuries: chondral injury due to overuse osteoarthritis and/or in the conservative treatment of meniscal injury.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/10/2018, the ethics committee for clinical research of the Catalan sports council (Consell Catalá de l'Sport, Av. Països Catalans, 40-48, 08950, Esplugues del Llobregat, Barcelona, Spain; +34 (0)609390346; dbrotons@gencat.cat), ref: 16/2018 CEICEGC

Study design
Epidemiological non-intervention study collecting retrospective and prospective, descriptive and multicenter information

Primary study design
Observational

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Knee osteoarthritis, meniscal tear

Interventions
The study recruited patients over 18 years of age, of both sexes, who have undergone intra-articular treatment with mobile reticulum hyaluronic acid for chondral knee injury due to mild to moderate knee osteoarthritis due to overuse syndrome or in conservative treatment of the knee. knee meniscal injury and who go to the doctor for their first follow-up visit after the intra-injections.

Information was collected longitudinally for 3 months for patients with meniscal tear and 6 months for patients with knee OA (KOA). At the inclusion visit (10 days after the last injection of Hymovis) the pain and functionality of the knee that the patients had before undergoing the treatment were evaluated using the Visual Analog Scale (VAS), Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and Knee Injury and Osteoarthritis Outcome Score (KOOS) questionnaires. Follow-up visits were 1, 2 and 3 months for the meniscal tear (MT) group and 1, 2, 3, and 6 months for the KOA and mixed group. Patients completed written questionnaires of VAS, WOMAC and KOOS at all follow-up visits. Written questionaries of QoL and patient satisfaction were given at 3 months follow-up (MT group) and 6 months (KOA and mixed group). During the inclusion and follow-up visits, the researchers collected sociodemographic and objective and subjective clinical data, as well as the use of concomitant medication. The evaluations could be performed within a time window of ±7 days. Participants agreed to interrupt NSAID consumption at least 24 h before each visit for the entire study.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Hymovis

Primary outcome(s)
1. Quality of life (QoL) determined using several instruments, including the KOOS score, WOMAC score, Patient's Global Improvement Impression Scale (PGI-I), ad hoc QoL single question
2. Physical activity determined using specific sub-dimensions from KOOS: activities of daily living (ADL), sport and recreation (Sport/Rec)
3. Satisfaction with the HA treatment evaluated using a visual analogue scale of satisfaction and an ad-hoc questionnaire
Measured at 1, 2 and 3 months for the MT group and 1, 2, 3 and 6 months for the KOA and mixed group

Key secondary outcome(s))
1. Pain in the previous 7 days to the visit measured using the VAS score
2. Local tolerability at the site of injection of the viscosupplementation product assessed through retrospective collection considering redness and pain occurring in the minutes following treatment sessions
3. Systemic adverse events recorded during the follow-up visits
Measured at 1, 2 and 3 months for the MT group and 1, 2, 3 and 6 months for the KOA and mixed group

Completion date
30/12/2020

Eligibility

Key inclusion criteria
The study population comprised patients (male or female) older than 18 years seen at one of the participating clinics between December 2018 and July 2019 for their first follow-up visit after intra-articular injection of mobile reticulum hyaluronic acid due to:
1. Mild to moderate symptomatic knee osteoarthritis responding to clinical and radiological criteria of American College of Rheumatology (ACR) and a Kallgren and Lawrence (KL) score II/III evidenced by radiography and/or MRI. Patients received two consecutive intra-articular injections of HYMOVIS (3 ml syringe with 8 mg of non-cross-linked HA alkylamida HYADD4; FIDIA Farmaceutici, Italy) given at 1-week intervals according to the prospect.
2. Knee meniscal tear (traumatic or degenerative) objectifiable by radiography and/or MRI. Patients received two consecutive intra-articular injections of HYMOVIS given at 2-week intervals according to the prospect.
3. Mild to moderate symptomatic knee osteoarthritis with meniscal tear. Patients received two consecutive intra-articular injections of HYMOVIS given at 1-week intervals according to the prospect.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
165

Key exclusion criteria
1. Viscosupplementation or corticosteroid therapy in the last 6 months
2. Concomitant diseases that could interfere with the tests during the data collection period or that could lead to erroneous results (i.e., rheumatoid arthritis, metabolic bone diseases, gout, Paget's disease of bone, symptomatic chondrocalcinosis)
3. Knee arthroplasty or other knee surgery in the last 12 months
4. Any scheduled surgery during the data collection period
5. Evidence or suspicion of infection in the affected joint or skin diseases of the knee, such as dermatitis or psoriasis
6. Patients with bilateral knee OA

Date of first enrolment
01/12/2018

Date of final enrolment
30/07/2019

Locations

Countries of recruitment
Spain

Study participating centre
Centre de Tecnificació Esportiva de la Residencia Blume
Consell Català de l'Esport
Generalitat de Catalunya.
Av. dels Països Catalans, 40-48
Esplugues de Llobregat
Barcelona
Spain
08950

Sponsor information

Organisation
Centre de Tecnificació Esportiva de la Residencia Blume

Funder(s)

Funder type
Industry

Funder Name
MSK Diagstic i Doncència`. SLP

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and /or analyzed during the current study are/will be available upon request from Dr Ramon Balius Matas (amonbaliusmatas@gmail.com)

IPD sharing plan summary
Available on request