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Safety and performance of trehalose hyaluronic acid versus standard infiltrative therapy based on medium weight sodium hyaluronate in knee joint osteoarthritis treatment

Submission date
09/09/2021

Recruitment status
No longer recruiting

Registration date
30/09/2021

Overall study status
Completed

Last Edited
09/11/2023

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Knee osteoarthritis is a disease affecting the knee joint that gets worse over time. It can lead to stiffness and swelling of the knee and can cause pain. Hyaluronic acid is used as a treatment for patients with knee osteoarthritis that continues to cause pain after standard treatment. This study intends to study a new version of hyaluronic acid. Trehalose is a chemical used to stabilize the composition of many pills and eye drops. Recently, there have been laboratory studies that show that trehalose helps hyaluronic acid remain stable and is safe and approved by the FDA when used with hyaluronic acid. This means that it, in combination with trehalose, hyaluronic acid does not break down as quickly, so could last for longer in the body, and provide pain relief for a longer period of time.

Who can participate?
Adults aged 21 years old and older with persistent knee pain due to osteoarthritis that has not been reduced with standard therapy (medicine, rehabilitation, and rest) for 6 months.

What does the study involve?
Participants will be allocated to one of two groups, with an equal chance of being in either group (like tossing a coin). Participants and researchers will not have a choice in the treatment given. In one group the patients will be injected in the knee with the standard hyaluronic acid. In the other group, patients will be injected with hyaluronic acid with added trehalose. Participants will not know which treatment they have received during the study and neither will the doctors administering their treatment.

What are the possible benefits and risks of participating?
It is hoped that a benefit of participating will be that patients are able to achieve longer-lasting results of pain relief or pain reduction if combined with trehalose. This product is safe, so no adverse reactions are expected.

Where is the study run from?
OASI Bioresearch Foundation (Italy)

When is the study starting and how long is it expected to run for?
From February 2019 to October 2021

Who is funding the study?
OASI Bioresearch Foundation (Italy)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Efficacy evaluation of trehalose-hyaluronic acid versus non-trehalose hyaluronic acid in persistent symptomatic knee osteoarthritis patients, with outcome measurement comparison of KOOS, IKDC, and VAS score at basal, 3 and 6 months

Study objectives
It is hypothesized that in vivo trehalose-hyaluronic acid (T-HA) has longer-lasting clinical results than non-trehalose hyaluronic acid (NT-HA) when applied as an injectable formula for osteoarthritis (OA) symptomatic knees.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/05/2019, OASI Institutional review board (via GA Amadeo Milano 20133 Italy; +39 (0)270124931; info@oasiortopedia.it), ref: not applicable

Study design
Single-centre prospective double-blinded randomized control trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Osteoarthritis of the knee

Interventions
Participants are randomized with an allocation ratio of 1:1 to receive either T-HA or NT-HA. The manufacturer provided the products labelled as A or B (corresponding to group A or B, respectively). Both products had the same syringe, color (transparent), texture, and quantity (2 ml). In this way, the study was blinded for patients, clinicians, researchers, and the manufacturer who handled the product. The nature of the product was revealed only when the study was finished. Each patient received three doses separated within 15 days.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Hyaluronic acid

Primary outcome(s)
Treatment performance measured using the Knee Injury and Osteoarthritis Outcome Score (KOOS), International Knee Documentation Committee (IKDC), and Visual Analogue Scale (VAS) at baseline, 3, and 6 months

Key secondary outcome(s))
Safety measured using adverse reactions recorded for the duration of the trial

Completion date

01/10/2021

Eligibility

Key inclusion criteria
1. Aged 18 to 80 years
2. Symptomatic knee osteoarthritis, grade I to III according to Kellgren and Lawrence classification
3. Without pain relief after at least 3 months of non-invasive treatment
4. Osteoarthritis diagnosed by x-ray and classified according to Kellgren and Lawrence classification

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
80 years

Sex
All

Total final enrolment
60

Key exclusion criteria
1. Any recent intra-articular injection therapy
2. Knee instability
3. Significant axial deviation
4. Systemic disorders such as rheumatoid arthritis, coagulopathies, or infections

Date of first enrolment
01/06/2019

Date of final enrolment
01/04/2021

Locations

Countries of recruitment
Italy

Study participating centre
OASI Bioresearch Foundation
via Amadeo GA 24 1-2
Milano
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Sponsor information

Organisation
OASI Bioresearch Foundation

ROR
https://ror.org/048qh2s42

Funder(s)

Funder type
Research organisation

Funder Name
OASI Bioresearch Foundation

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from fellow@oasiortopedia.it.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/09/2022	09/11/2023	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes