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Combining two Hyaluronic Acids with different characteristics: a randomised, double-blind, placebo controlled trial

Submission date	Recruitment status	[ ] Prospectively registered
23/10/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/10/2007	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
28/10/2008	Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
2 HAs

Study objectives
Combined Hyaluronic Acids (HA) will improve clinical outcomes more than a single HA.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Research Ethics Board of the University of Western Ontario on the 10th September 2006 (ref: # 166732).

Study design
Randomised, placebo-controlled, double-blind prospective design

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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

Interventions
Patients were randomised to receive one of four treatments:
1. Lower Molecular Weight HA (LMW)
2. Higher Molecular Weight HA (HMW)
3. Combined lower and higher molecular weight and different concentrations (DMW)
4. Saline placebo

Physicians and patients were blinded to assignment (syringes were covered to conceal any details of product or volume). Low molecular weight solution of HA was a marketed product of 0.50 - 0.73 x 10^6 Daltons and the high molecular weight HA was a marketed product of 6 million kDa, both indicated for intra-articular injection for knee osteoarthritis. 2 ml of LMW and HMW were injected using an aseptic technique and a medial approach. No anaesthetic was used either

topically or intra-articularly. Each injection was performed one week apart (± 2 days) by an experienced clinician. All injections were initiated after baseline and follow-up assessments of Visual Analogue Scale (VAS) and global satisfaction which were performed by an independent technician.

The DMW preparation consisted of 0.7 ml of sterile 2.2% LMW (0.58 - 0.78 x 10^6 Daltons) sodium hyaluronate and 0.7 ml of sterile 1% HMW (1.2 - 2.0 x 10^6 Daltons) sodium hyaluronate. Viscoelastics were separated by a Debiopass stopper within a pre-filled 3 ml sterile syringe. Injection was conducted as for the LMW and HMW preparations as described above. Patients were free to seek additional therapeutic modalities including physical therapy and analgesics (including Non-Steroidal Anti-Inflammatory Drugs [NSAIDs]) but not intra-articular therapies prior to their presentation for follow-up. All concomitant treatments were recorded. All assessments were conducted at baseline V1, and prior to each injection at visits 2, 3 and 4, and follow-up visits at 4 (V5), 12 (V6) and 16 (V7) weeks.

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome measure
Improvement in self-paced 40-m walking pain using the Visual Analogue Scale (VAS), measured at V1 - V7.

Timepoints:
V1 = Baseline
V2 = Week 1
V3 = Week 2
V4 = Week 3
V5 = Week 4
V6 = Week 12
V7 = Week 16

Secondary outcome measures
1. Improvement in seated rest pain Visual Analogue Scale (VAS), measured at V1 - V7
2. Patient global satisfaction using a 5-point numerical scale, with 1 representing not satisfied and 5 completely satisfied, measured at V1 - V7
3. Presence of adverse events and concomitant medications, measured at V1 - V7

Timepoints:
V1 = Baseline
V2 = Week 1
V3 = Week 2
V4 = Week 3
V5 = Week 4
V6 = Week 12
V7 = Week 16

Overall study start date
01/01/2007

Completion date
01/07/2007

Eligibility

Key inclusion criteria
1. Radiographic evidence of grade 1 to 3 medial compartment Osteoarthritis (OA)
2. Did not exhibit non-arthritis related disease
3. Gave consent as approved by the University of Western Ontario Ethics Review Board
4. Age range at recruitment was 45 - 85 years, both men and women

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
200

Key exclusion criteria
1. Previous injection with HA or corticosteroids
2. Bilateral knee OA
3. Unstable cardiovascular or metabolic disease
4. Unable to commit to follow-up period

Date of first enrolment
01/01/2007

Date of final enrolment
01/07/2007

Locations

Countries of recruitment
Canada

Study participating centre
801 Commissioners Road
London
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Sponsor information

Organisation
Lawson Health Research Institute (Canada)

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801 Commissioners Road East
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Sponsor type
Research organisation

Website
http://www.lhrionhealth.ca

ROR
https://ror.org/051gsh239

Funder(s)

Funder type
Research organisation

Funder Name
Lawson Health Research Institute (Canada)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2008		Yes	No