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 [] Statistical analysis plan Registration date Overall study status 30/10/2007 Completed [X] Results [] Individual participant data Last Edited Condition category Musculoskeletal Diseases 28/10/2008

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number N/A

Study information

Scientific Title

Acronym

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

- 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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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 Canada N6C 5J1

Sponsor information

Organisation

Lawson Health Research Institute (Canada)

ROR

https://ror.org/051gsh239

Funder(s)

Funder type

Research organisation

Funder Name

Lawson Health Research Institute (Canada)

Results and Publications

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