

Efficacy of intra-articular polynucleotides in the treatment of knee osteoarthritis

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		<input type="checkbox"/> Protocol
Registration date 20/04/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 20/04/2009	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
plinart 02/06

Study information

Scientific Title
Efficacy of intra-articular polynucleotides in the treatment of knee osteoarthritis: a controlled, randomised, double-blind clinical trial

Study objectives

The ideal intra-articular treatment for osteoarthritis (OA) should not only provide a mechanical protection of the cartilage surface, but also restore chondrocytes' homeostasis by restoring the physiological articular micro-environment and supplying nutrients.

Polynucleotides (PN) are polymeric molecules which are able to bind a large amount of water and to re-organise their structure by orienting and co-ordinating water molecules to form a 3-D gel. Polynucleotides when infiltrated at intra-articular level, can deeply moisturise articular surfaces. Polynucleotides, simple nucleotides, nucleosides and nitrogen bases are physiologically present in the extra-cellular environment and are useful substrates for cells. Intra-articular infiltration progressively enriches the synovial fluid of PN and thus of nucleotides, purine and pyrimidine bases that tissues can use to promote physiological repair mechanisms.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Ethics Committee of the Clinical Centre (IRCCS Foundation, Orthopaedic and Traumatology Department, S. Matteo Hospital Institute, University of Pavia, Pavia-Italy) approved on the 10th October 2006 (ref: 256)

Study design

Randomised controlled double-blind parallel group clinical trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Knee osteoarthritis

Interventions

The product under study is a class III medical device, a gel, consisting of highly purified - natural origin long chain polynucleotides (20 mg/ml concentration). It is marked in a pre-filled glass syringe with 2 ml of high molecular weight sterile and apirogenic polynucleotides (batch n° 605553), trade name Turnover Joint and Condrotide (Mastelli Srl, Italy).

Control group was treated with hyaluronic acid (HA) in pre-filled glass syringe with 2 ml of 8 mg /ml hyaluronic acid (Sinovial, batch n° 050727, Laboratoires Genévrier, Sophia Antipolis, France).

Patients of Group A (treatment group) received five 2 ml intra-articular injections with an interval of one week between the injections (from week 0 to week 4) of 40 mg/2 ml polynucleotides.

Group B patients (control group) received five 2 ml intra-articular injections with an interval of one week between the injections (from week 0 to week 4) of 16 mg/2 ml hyaluronic acid.

Intervention Type

Drug

Phase

Phase IV

Drug/device/biological/vaccine name(s)

Long chain polynucleotides

Primary outcome(s)

Change in the pain level at rest, at weight-bearing, and during physical activity, at all timepoints from baseline (T0) to T16.

Timepoints:

T0: Inclusion visit

T1: After one week

T2: After two weeks

T3: After three weeks

T4: After four weeks (end of treatment period)

T8: First follow-up visit, after eight weeks

T16: End of the trial, after 16 weeks

Key secondary outcome(s)

1. Evaluation of Knee Osteoarthritis Outcome Score (KOOS) results, measured at T0, T4, T8 and T16

2. Non-steroidal anti-inflammatory drug (NSAID) consumption, at all timepoints from baseline (T0) to T16

3. Crackling during movement and articular mobility limitation (LMA), at all timepoints from baseline (T0) to T16

4. Safety profile of the devices, assessed by recording adverse events at each visit

Timepoints:

T0: Inclusion visit

T1: After one week

T2: After two weeks

T3: After three weeks

T4: After four weeks (end of treatment period)

T8: First follow-up visit, after eight weeks

T16: End of the trial, after 16 weeks

Completion date

20/12/2007

Eligibility**Key inclusion criteria**

1. Aged between 18 and 80 years, either sex

2. Affected by knee osteoarthritis (diagnosis based on the American College of Rheumatology [ACR] classification)

3. Developed persistent pain for at least two months

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Alcohol or drug abuse
2. Pregnancy or breastfeeding
3. Hypersensitivity to study products
4. Hyaluronic acid or steroid infiltration therapy ongoing or suspended for less than 3 months
5. Systemic treatment with anticoagulants and steroids ongoing or suspended for less than 1 month
6. Previous bone fractures or severe traumas of the interested knee
7. Presence of rheumatoid arthritis and of relevant haematological pathologies

Date of first enrolment

01/12/2006

Date of final enrolment

20/12/2007

Locations**Countries of recruitment**

Italy

Study participating centre

IRCCS Foundation

Pavia

Italy

27100

Sponsor information**Organisation**

Mastelli Srl (Italy)

ROR

<https://ror.org/003r56a21>

Funder(s)

Funder type

Industry

Funder Name

Mastelli Srl (Italy)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration