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

Submission date	Recruitment status	[ ] Prospectively registered
09/04/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/04/2009	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
20/04/2009	Musculoskeletal Diseases	[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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-enivronment 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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
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

Secondary outcome measures
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

Overall study start date
01/12/2006

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Alcohol or drug abuse
2. Pregnancy or breastfeeding
3. Hypersensibility 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)

Sponsor details
Via bussana vecchia 32
Sanremo
Italy
18038

Sponsor type
Industry

Website
http://www.mastelli.it

ROR
https://ror.org/003r56a21

Funder(s)

Funder type
Industry

Funder Name
Mastelli Srl (Italy)

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