ISRCTN77293496 https://doi.org/10.1186/ISRCTN77293496

# 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