ISRCTN55861167 https://doi.org/10.1186/ISRCTN55861167

Comparison between intraarticular ozone and a placebo in the treatment of knee arthritis

Submission date
23/10/2010

Recruitment status
No longer recruiting

Registration date
08/11/2010

Overall study status
Completed

Last Edited
12/01/2017

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Osteoarthritis (OA) is the most common type of arthritis, affecting millions of people worldwide. It occurs when the protective cartilage on the end of bones wears away. The bones then rub against one another, which can cause stiffness, pain and a reduction in a person's range of movement. One of the most common joints to be affected is the knee, and in many sufferers, the pain prevents people from moving around leading to muscle weakness and disability. There are a variety of treatments for knee OA, including exercise, medication and surgery (knee replacement). One promising new treatment is the injection of ozone into the knee joint to help alleviate pain. Ozone is a gas made up of three atoms of oxygen joined together, rather than the usual two atoms as found in the oxygen we breathe from the air. The aim of this study is to find out whether ozone injections into the affected knee joint are an effective treatment for knee OA.

Who can participate?
Patients aged between 60 and 85 who have knee OA.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive eight, weekly injections of ozone into the knee joint. Those in the second group have a placebo (dummy), consisting of normal air injected into the knee joint. At the start of the study and then again after four week, eight weeks and two months, patients in both groups have their pain levels assessed using a range of questionnaires.

What are the possible benefits and risks of participating?
Participants who receive the ozone injections may benefit from an improvement to their pain levels and OA symptoms. There is a small risk of pain in the knee during and after injections.

Where is the study run from?
1. Paulista School of Medicine – Federal University of São Paulo (Brazil)
2. Pró-Vida – Center for Total Health Assistance LLC (Brazil)
3. University of Santo Amaro – Medicine College (Brazil)

When is the study starting and how long is it expected to run for?
February 2010 to June 2015

Who is funding the study?
Sao Paolo Medical School (Brazil)

Who is the main contact?
Professor Carlos César Lopes de Jesus
caceloje@gmail.com

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
NCT29102010

Study information

Scientific Title
Comparison between intraarticular ozone and a placebo in the treatment of knee arthritis: A double blind, randomised placebo controlled trial

Acronym
INOPKA

Study objectives
Hypothesis as of 30/12/2016:
Ozone is more effective than a placebo in the treatment of knee osteoarthritis concerning pain relief, improvement of joint function and quality of life.

Original hypothesis:
Ozone is more affective than placebo in the treatment of knee arthritis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Ethical Review Board of the Paulista School of Medicine – Federal University of Sao Paulo, 08 /12/2010, ref: EPM-UNIFESP

Study design
Randomised double-blinded placebo controlled clinical trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Knee osteoarthritis

Interventions
Interventions section as of 11/01/2017:
Study participants attend a baseline visit at which the following procedures are performed: medical history, physical examination, analysis of X-ray of the affected knee and application of the following questionnaires and tests: Visual Analogue Scale (VAS), Geriatric Pain Measure (GPM), Lequesne's Index, Timed Up and Go Test (TUG Test), Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), and Short-Form Health Survey (SF-36). Eligible patients are fully informed of the purpose of the study. All patients that fulfill the inclusion criteria signed the informed consent prior to enrolment in the trial. They are instructed to continue their medical treatment according to their physicians' orientations.

With the objective of avoiding selection bias, all included participants are sequentially assigned by the researchers to receive OZ or PBO according to a pre-established computer-generated global randomization list. This is carried out in such a manner as to guarantee each patient an equal chance of receiving the intervention. The randomization list is generated using software ETCETERA, version 2.46, and constituted 98 numbers with the corresponding treatments. Prior to the beginning of the randomization it has been stipulated that group A would be the ozone group and B, the placebo group.

Ozone group (OZ): Participants receive one intra articular injection of ozone 20 µg/ml (10ml) per week for 8 consecutive weeks.

Placebo group (PBO): Participants receive one intra articular injection of 10 ml of air per week for 8 consecutive weeks.

Assessments are performed at baseline (visit 1), 4 weeks (visit 2), 8 weeks (visit 3), and 8 weeks after the end of the injections (visit 4). At the follow-up visits, the same procedures as those described for visit 1 are performed.

Original interventions section:
Patients will be randomized to receive either intra articular ozone, 20µg/ml once a week for 8 consecutive weeks, or intra articular air, once a week, for 8 consecutive weeks.

The follow-up will last for 2 months after the last session of treatment.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Ozone

Primary outcome(s)
Primary outcome measures as of 30/12/2016:
Reduction of pain measured according to
1. Visual Analogue Scale (VAS)
2. Lequesne Algofunctional Index
3. Geriatric Pain Measure (GPM)

All outcomes will be measured at baseline, 4 and 8 weeks and 2 months.

Original primary outcome measures:
Efficacy of treatment measured according to
1. Lequesne Algofunctional Index
2. Time Up and Go Test
3. Activities of Daily Living (ADLs)
4. Medical Outcomes Study 36-Item Short Form
5. Health Survey (MOS SF36 Health Survey)
6. Visual Analogue Scale (VAS)
7. Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC Index)

All outcomes will be measured at baseline, 4 and 8 weeks and 2 months.

Key secondary outcome(s))
Secondary outcome measures as of 30/12/2016:
Improvement of joint function and quality of life according to:
1. Time Up and Go Test
2. Medical Outcomes Study 36-Item Short Form
3. Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC Index)

All outcomes will be measured at baseline, 4 and 8 weeks and 2 months

Original secondary outcome measures:
Pain reduction according to
1. Lequesne Algofunctional Index
2. VAS
All outcomes will be measured at baseline, 4 and 8 weeks and 2 months.

Completion date
30/06/2015

Eligibility

Key inclusion criteria

Inclusion criteria as of 30/12/2016:
1. Patients from Outpatients Department of Geriatrics and Gerontology Discipline – Paulista School of Medicine – Federal University of Sao Paulo, Pro-Vida – Centro de Assistencia Integral a Saude, and Outpatients Department – Rheumatology Discipline – Medical College – Santo Amaro University
2. Aged between 60 years and 85 years
3. Clinically and radiologically confirmed knee osteoarthritis according to the American College of Rheumatology (ACR) criteria

Original inclusion criteria:
1. Patients from Outpatients Department of Geriatrics and Gerontology Discipline da Escola Paulista de Medicina - Universidade Federal de São Paulo
2. Aged more than 60 years or less than 85 years
3. Clinically and radiologically confirmed knee arthritis according to the American College of Rheumatology (ACR) criteria

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Key exclusion criteria
Exclusion criteria as of 30/12/2016:
1. Patients from Outpatients Department of Geriatrics and Gerontology Discipline – Paulista School of Medicine – Federal University of Sao Paulo, Pro-Vida – Centro de Assistencia Integral a Saude, and Outpatients Department – Rheumatology Discipline – Medical College – Santo Amaro University,
2. Aged between 60 years and 85 years, and
3. Clinically and radiologically confirmed knee osteoarthritis according to the American College of Rheumatology (ACR) criteria.

Original exclusion criteria:
1. Patients aged less than 60 years or more than 75 years
2. Will not give their permission to be included in the study
3. Patients with mental and/or neurologic deficit
4. Diagnosis of secondary osteoarthrosis, patients with recent knee traumas or
5. Suspected associated knee lesion
6. Patients with coxofemoral articulation affections
7. In the acute phase of the disease

Date of first enrolment
19/11/2010

Date of final enrolment

23/03/2015

Locations

Countries of recruitment
Brazil

Study participating centre
Paulista School of Medicine – Federal University of São Paulo (EPM – UNIFESP)
Outpatients Department – Geriatrics and Gerontology Discipline
Rua Prof. Francisco de Castro, 105
São Paulo
Brazil
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Study participating centre
Pró-Vida – Center for Total Health Assistance LLC
Av. Paes de Barros, 411 – cj. 14 e 15
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Study participating centre
University of Santo Amaro – Medicine College
Outpatients Department – Rheumatology Discipline
Rua Cássio de Campos Nogueira, 2031
São Paulo
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04829-310

Sponsor information

Organisation
Sao Paolo Medical School (Escola Paulista de Medicina) (Brazil)

ROR
https://ror.org/036rp1748

Funder(s)

Funder type
University/education

Funder Name
Sao Paolo Medical School (Escola Paulista de Medicina) (Brazil)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Carlos César Lopes de Jesus (caceloje@gmail.com).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		11/01/2017	12/01/2017	No	No
Participant information sheet		31/12/2016	04/01/2017	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes