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A study to compare the efficacy of intra-articular injection of methylprednisolone versus triamcinolone hexacetonide in patients with knee osteoarthritis

Submission date
16/09/2013

Recruitment status
No longer recruiting

Registration date
25/09/2013

Overall study status
Completed

Last Edited
10/06/2016

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Steroids can be used in the treatment of patients with knee osteoarthritis (arthritis of the knee), but the best agent is still unknown. This study aimed to compare the effect of two drugs (triamcinolone hexacetonide and methylprednisolone acetonide) on the condition.

Who can participate?
Men and women who are at least 40 years old, with painful knee osteoarthritis took part in this study.

What does the study involve?
Participants were randomly allocated to receive a single knee injection of either triamcinolone hexacetonide or methylprednsilone acetonide. After 24 weeks participants attended a follow-up visit to assess the effectiveness of the treatment with questionnaires.

What are the possible benefits and risks of participating?
Possible benefits were pain relief and physical function improvement. Risks were related to the injection and included pain, swelling, bleeding and infection in the knee.

Where is the study run from?
The study was run from Hospital Heliópolis, São Paulo, Brazil

When is the study starting and how long is it expected to run for?
The study started in December 2010 and ended in May 2013

Who is funding the study?
The investigators funded the study

Who is the main contact?
Dr Andrea Lomonte
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomized, double-blind study to evaluate the efficacy of intra-articular injection of methylprednisolone versus triamcinolone hexacetonide in patients with knee osteoarthritis

Study objectives
Intra-articular injections of methylprednisolone acetate and triamcinolone hexacetonide have similar efficacy at reducing knee pain and improving physical function both in the short as in the long-term in patients with symptomatic knee osteoarthritis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee of the Hospital Heliopolis [Comitê de Ética em Pesquisa do Hospital Heliópolis], 14/10/2008

Study design

24 weeks prospective randomized two arms double-blinded study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Interventions
1. Intra-articular triamcinolone hexacetonide 40mg single dose
2. Intra-articular methylprednisolone acetate 40mg single dose

Total duration of the study: 24 weeks
Intervention was one day (single injection)
Follow-up: 24 weeks

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Methylprednisolone, triamcinolone hexacetonide

Primary outcome measure
Mean change from baseline in patients assessment of pain in the targeted knee by VAS at week 4

Secondary outcome measures
1. Mean changes from baseline in patients assessment of pain by VAS at 12 and 24 weeks
2. Mean changes from baseline in patients and physicians global assessment of disease activity by VAS
3. Improvement in patients global assessment of disease by Likert scale
4. Mean changes from baseline in total Western Ontario and McMaster Universities (WOMAC) questionnaire and its subscores of pain, stiffness and physical function
5. Mean changes from baseline in total Lequesne algofunctional index

6. Outcome Measures in Rheumatology Clinical Trials and Osteoarthritis Research Society International (OMERACT-OARSI) response criteria
7. Analysis of predictors of response

All secondary outcomes were measured at 4, 12 and 24 weeks.

Overall study start date
18/12/2010

Completion date
17/05/2013

Eligibility

Key inclusion criteria
1. Diagnosis of knee osteoarthritis (OA) according to the American College of Rheumatology criteria
2. Kellgren-Lawrence radiographic grade II or III of the knee
3. Visual analogue scale (VAS) for knee pain of at least 40mm (maximum 100mm)
4. Both genders, aged 40 years or older
5. Failure to control OA symptoms with previous or current analgesics and/ or non steroidal antiinflammatory drugs

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Other rheumatic or inflammatory condition
2. Symptomatic disease of the lower limbs (other than knee OA)
3. Serious and/or uncontrolled concomitant medical illness
4. Body mass index (BMI) greater or equal to 35kg/m2
5. IA injection of corticosteroid or hyaluronic acid in the previous 6 months
6. knee replacement in the targeted joint
7. Local or systemic infection
8. Pregnancy
9. Skin lesions in the IA injection site
10. Physical therapy for the knee
11. Known hypersensitivity to corticosteroids or lidocaine; and the use of anticoagulants

Date of first enrolment
18/12/2010

Date of final enrolment
17/05/2013

Locations

Countries of recruitment
Brazil

Study participating centre
Rua Maria Bucalem Haddad
Sao Paulo
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04125-010

Sponsor information

Organisation
Hospital Heliópolis (Brazil)

Sponsor details
Rua Cônego Xavier
276 - Sacomã
Sao Paulo
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04231-902

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01bkdwe73

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded (Brazil)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2015		Yes	No