Fermathron plus versus placebo.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28570

Source
Nationaal Trial Register

Brief title
N/A

Health condition

Mild to moderate OA of the knee (Kellgren 1, 2 and 3)

Sponsors and support

Primary sponsor: Maatschap orthopedie St. Annaziekenhuis
Source(s) of monetary or material Support: Hyaltech LTD, Edingburgh, Scotland
Biomet Nederland

Intervention

Outcome measures

Primary outcome

Efficacy endpoints: Pain

Pain is measured using a VAS score. The investigator will ask the patient to walk 50 meters and asks for the pain. Also, the investigator will ask for the pain at rest and have the patient mark this score using VAS measurement.
Successful treatment is defined as a reduction in pain of ¡Ý 25% in using the VAS score

following a 50 meter walk test compared to baseline score at Visit 2. Patients, who have this amount of pain reduction or more, are classified as responders.

Efficacy endpoints: Function

Function is measured using the C subscale of the WOMAC questionnaire.
Successful treatment is defined as an improvement in function of ¡Ý 25% in using the C subscale of the WOMAC questionnaire compared to baseline score (Visit 2).

Efficacy endpoints: Safety

Safety is measured with recording of AE¡¯s during the study.

All adverse events will be recorded. Evaluator will identify if the condition is device-related and if device related, determine the level of severity ("mild", "moderate", and "severe"). Comparison between treatment groups on all adverse events, device-related adverse events, and their severity will be conducted.

Secondary outcome

1. WOMAC A subscale for pain;

2. WOMAC B subscale for joint stiffness;

3. Patient satisfaction with treatment result;

4. Use of escape medication;

5. Changes in limitations in sports and work.

Study description

Background summary

The department of orthopedic surgery of the St. Anna hospital started in 2006
with intra-articulair injecting of hyaluronic acid (Fermathron) as the standard

treatment for patients with mild osteoarthritis of the knee. So far, the

Knowledge Centre for Orthopedic Surgery has carried out a prospective registration study of all patients treated with hyaluronic acid within this hospital. Analys of this data indicates that Fermathron is safe and possibly effective in the treatment of mild knee OA. To gather more evidence on the effectiveness and safety of these hyaluronic acid injections, this double blind, placebo-controlled study is designed. This study will compare Fermathron plus with respect to clinical outcomes and safety to a placebo-treatment. This will provide evidence for the present treatment of patients with mild knee OA in our orthopedic department and collegues can be informed with presentations.

Objective of the study:

To prove superiority of Fermathron plus in the treatment of patients with mild knee OA compared to placebo

Study design:

This study is designed as a double blind, placebo-controlled study. Patients are randomised to either a treatment group (3 injections with Fermathron plus) or the placebo-group (3 injections with saline).

Study objective

Fermathron plus significantly improves pain and function in patients with knee OA compared to placebo.

Study design

1. Baseline injection, week 1;

2. Injection 2, week 2;

3. Injection 3 week 3;

4. 1 month follow up;

5. 2 months follow up;

6. 3 months follow up;

7. Last visit at 6 months follow up.

Intervention

Eligible patients giving written informed consent will be randomized to receive 3 injections of either the investigational device (Fermathron plus) or the placebo-control device (phosphate-buffered saline). Injections will be administered at weekly intervals (Visits 2, 3, and 4).

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients who are legally competent and able to understand the nature, scope and aim of the clinical investigation and have given written informed consent to participate;

2. Patients of either sex and of all races who have been diagnosed as having osteoarthritis of the knee according to the American College of Rheumatology diagnostic criteria for OA (Attachment 1);

3. Patients may have osteoarthritis in one or both knees. For patients with bilateral OA, the

more severely affected knee will be included in the study. If both knees are similarly affected (defined as ¡Ü 25mm difference between left and right side on VAS score for pain after the 50 meter walk test), the patient will be excluded;

4. Patients with OA of the knee which has been radiographicly confirmed, within the previous 12 months, as being of Grade I, II or III according to the Kellgren-Lawrence Classification (Attachment 2);

5. Patients having pain in the knee with a baseline score of 15 mm or more on a 100 mm visual analogue scale for the 50 meter walk test;

6. Patients for whom, in the view of the investigator, it is clinically acceptable to withdraw all NSAIDs and analgesics and rely on acetaminophen as the only escape medication for the duration of the study;

7. Patients who are able and willing to return for follow-up evaluations;

8. Patients with bilateral OA with ¡Ý 25mm difference in VAS score between right and left knee, who agree that the other knee will not be treated during the course of this study.

Exclusion criteria

1. Patients with osteoarthritis in one or both knees which has been radiographicly confirmed, within the previous 12 months, as being of grade IV according to the Kellgren-Lawrence Classification (Attachment 2);

2. Patients with associated osteoarthritis of either hip or any other condition that might interfere with the assessment of effectiveness;

3. Patients with psychosomatic complaints defined as a VAS-score for pain after the 50 meter walk test of ¡Ý 90mm;

4. Patients with rheumatoid arthritis or other inflammatory arthritis as defined by the American College of Rheumatology diagnostic criteria for RA (Attachment 3);

5. Patients with a known hypersensitivity to sodium hyaluronate or acetaminophen;

6. Patients unwilling to stop all nonsteroidal, anti-inflammatory drugs (NSAIDs) and osteoarthritis analgesics, and rely on escape medication only for 7 days prior to the first injection and for the duration of the study;

7. Patients receiving regular analgesics/anti-inflammatory therapy, including acetaminophen, for reasons other than painful osteoarthritis of the knee. (Exception: Patients receiving low-dose acetylsalicylic acid, up to 325 mg daily, as prophylaxis for cardiovascular disease are eligible for inclusion in this study);

8. Patients who have had prior hyaluronic acid injections in any joint;

9. Patients who have had intra-articular injections of any type in the preceding three months;

10. Patients treated with arthroscopy within the previous three months;

11. Patients who have received any experimental drug or device within the previous three months;

12. Patients in whom the intra-articular route is contra-indicated;

13. Patients with an active or suspected infection in or around the knee;

14. Patients diagnosed with any of the following:

A. Arthritis of metabolic origins;

B. Chondromalacia;

C. Chronic active fibromyalgia;

D. Gout;

E. Osteonecrosis of either knee;

F. Knee instability;

G. Vascular insufficiency;

H. Severe renal or hepatic impairment.
15. Patients with other disease processes that require corticosteroid therapy;

16. Patients who are known alcohol or drug abusers;

17. Patients who are pregnant or lactating.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2009
Enrollment:	200
Type:	Anticipated

Ethics review

Positive opinion

Date:	16-03-2009
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL1629
NTR-old	NTR1726
Other	METC : 0745
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A