Does Fermatron plus improve pain and functioning in patients with knee OA compared to placebo?

Published: 26-02-2009
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To prove superiority of Fermathron plus in the treatment of patients with mild knee OA compared to placebo

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON31817

Source
ToetsingOnline

Brief title
Fermathron plus versus placebo

Condition

- Joint disorders

Synonym
degenerative joint disease, Osteoarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Sint Annaziekenhuis
Source(s) of monetary or material Support: Maatschap orthopedie St. Annaziekenhuis. Daarnaast sponsoring in materiaal (Fermathron plus en placebo) en ondersteuning (opstellen randomisatielijst) door Hyaltecht ltd.

Intervention

Keyword: Hyaluronic acid, knee, osteoarthritis, placebo

Outcome measures

Primary outcome

1. Pain in the affected knee

2. Restricions in daily activities due to the affected knee

Secondary outcome

1. Patient satisfaction with the applied treatment

2. Safety of the applied treatment.

3. Range of motion in the affected knee

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.

Study objective

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). Follow up consists of 4 follow up moments, the last one 6 months after the last injection.

Intervention

Included patients are randomised to either the treatment group (3 injections with Fermathron plus) or to the placebo group (3 injections with saline)

Study burden and risks

The HA in Fermathron plus is derived from a naturally occurring bacterium, which is not pathogenic in man, and there is no risk of transfer of animal viruses. The risk from bacterial antigens is minimized by the manufacturing process of continuous fermentation (in which there is minimal breakdown of cell components) together with rigorous purification. The sodium hyaluronate is produced as a capsule around the outside of the cell so that the cell does not have to be disrupted to release the product. The purification of the sodium hyaluronate has been optimized during manufacturing and is closely monitored to ensure the consistent removal of potential antigenic impurities. Previous clinical studies have shown that intra-articular injection of HA is very well tolerated and any adverse events related to the treatment are local and transient. To minimize the risk of any adverse effects associated with the procedure, all the investigators taking part in the study are experienced in the technique. Injections will be given with a lateral approach to a straight knee, this having a lower risk of adverse effects than other methods. Data from our own prospective group show that 5% of all treated

Contacts

Public
Sint Annaziekenhuis

Postbus 90
5660 AB
NL
Scientific
Sint Annaziekenhuis

Postbus 90
5660 AB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Mild osteoarthritis of the knee, Kellgren-Lawrence grade I-III

Exclusion criteria

Bilateral osteoarthritis of the knee
Pregnancy
Lactation
Infection of the knee
evidence of skin disease

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-06-2009
Enrollment:	200
Type:	Actual

Medical products/devices used

Generic name:	Intra articular viscosupplementation (hyalruonic acid)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	02-03-2009
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	26-10-2009
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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
CCMO	NL19495.015.07