Knee joint replacement over 5 years in patients with knee osteoarthritis. A long term follow up study in patients of the CL3-12911-018 study.

Published: 04-06-2012
Last updated: 26-04-2024

To collect data on knee joint replacement procedures or proceduresprac ticed in the knee (arthroscopy, osteotomy or other) over 5 years inpatients with knee osteoarthritis having participated in the CL3-12911-018 study and having received at least...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON37337

Source
ToetsingOnline

Brief title
long term follow up study in patients with knee osteoarthritis.

Condition

- Other condition

Synonym
knee osteoarthritis

Health condition

kniearthrose

Research involving

Human

Sponsors and support

Primary sponsor: Servier R&D Benelux
Source(s) of monetary or material Support: de sponsor : Institut de Recherches Internationales Servier

Intervention

Keyword: follow up, knee osteoarthritis

Outcome measures

Primary outcome

- Knee joint replacement in the target knee (knee followed in the CL3-

12911-018 study).

- Knee surgery or other procedure (arthroscopy, osteotomy or other).

Secondary outcome

NA

Study description

Background summary

Osteoarthritis (OA) is thought to be the most prevalent chronic joint disease. The incidence of OA is markedly rising with the ageing of the population and the epidemic of obesity. Cartilage degradation and loss, due to biomechanical and biochemical changes in the joint, are the major degenerative changes of OA. Pain and loss of function are the main clinical features that lead to treatment, including non-pharmacological, pharmacological and surgical approaches (1).

Over the past years, there have been considerable efforts to study new agents for their potential to improve symptoms and also alter the course of OA by delaying or reversing the progression of joint structural damage. However, the ultimate clinically relevant outcome for these structure modifying drugs would be to prevent or delay the joint replacement surgery.

According to the European guideline on clinical investigation of medicinal products used in the treatment of osteoarthritis (CPMP/EWP/784/97 Rev.1 dated 20 January 2010), the necessity of joint replacement is a recommended outcome to evaluate, although this outcome may not be a feasible endpoint within the frame of a Phase III clinical trial (2).

Knee joint replacement is an invasive procedure in which cartilage, bone and soft tissues are replaced by artificial materials. It often occurs after OA has been treated for a long period with drugs (usually analgesics to treat the pain), physical therapy (specific exercises that may help improve motility and pain) and salvage surgical procedures (3).

Little data on long-term progression of OA in large cohorts of patients with knee OA is available in the literature. The Group for the Respect of Ethics and Excellence in Science (GREES) organised a working group to assess the time to joint surgery. They concluded that existing data could suggest that criteria such as lack of progressive joint space narrowing (JSN) is predictive of not going to surgery (5) .
A study has been designed to evaluate the efficacy of Strontium Ranelate (1g and 2g per day) on the Joint Space Width (JSW) progression, as assessed by measuring the mean change in the JSW of the medial femoro-tibial compartment determined by X-ray. This study numbered CL3-12911-018 study and entitled: *The efficacy and safety of two doses of Strontium Ranelate (1g and 2g per day) versus placebo administered orally for 3 years in the treatment of knee osteoarthritis* started in 2006 and was completed in February 2011.

In order to evaluate the long term outcome of these patients with regards to knee surgery, a 5 year follow up study will be proposed to all patients with knee osteoarthritis having participated in the CL3-12911-018 study and having received at least one year (365 days) of CL3-12911-018 study treatment. Patients in this long term study will not receive any study drug and will be followed by their usual practioner, no study exams will be required. The only requirements for an initial visit will be to inform the patient about the study and obtain the patient*s informed consent. At all visits, patient*s weight, OA treatments and knee surgery/procedure history will simply be collected.

Study objective

To collect data on knee joint replacement procedures or procedures practiced in the knee (arthroscopy, osteotomy or other) over 5 years in patients with knee osteoarthritis having participated in the CL3-12911-018 study and having received at least one year (365 days) of CL3-12911-018 study treatment (Strontium Ranelate 1g/2g or placebo).

Study design

A 5 year international multicentric study in patients who have participated in the CL3-12911-018 study, having received the study treatment (strontium ranelate 1g/2g or placebo) for at least one year.
There will be no modification of the medical practice of the participating investigators and no additional examinations for the patients, medication will be prescribed solely as a result of a normal clinical evaluation. This study will not require any extra routine medical examination for the patient.
The study will be divided into the following periods :
-1 inclusion visit (M000)
-5 follow-up phone calls at 12,24,36,48 and 60 months (± 3 months time window will be allowed)

Study burden and risks

There are no risks related to this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

Patients included in the CL3-12911-018 study and having received the CL3-12911-018 study treatment (strontium ranelate 1g/2g or placebo) for at least one year (at least 365 days of treatment during the CL3-12911-018 study)
having signed the informed consent form for this new study

Exclusion criteria

-unlikely to cooperate in the study (such as patients suffering from dementia)
-patients unable to provide the information requested by the study

Study design

Design

Study phase:	3
Study type:	Observational non invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2012
Enrollment:	12
Type:	Actual

Ethics review

Approved WMO

Date:	04-06-2012

Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL39322.058.12