Survey of Osteoarthritis Real World Therapies (SORT)

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OBJECTIVE: Primary Objective:Among patients with symptomatic osteoarthritis of the knee(s) who are prescribed oral or topical analgesics for their symptoms, characterize over a 12-month follow-up period the clinical care and outcomes of patients who...

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

Summary

ID

NL-OMON38125

Source
ToetsingOnline

Brief title
SORT

Condition

- Joint disorders

Synonym
osteoarthritis of the knee

Research involving
Human

Sponsors and support

Primary sponsor: Syreon Corporation
Source(s) of monetary or material Support: Pharmaceutische Industrie

Intervention

Keyword: knee, Osteoarthritis, SORT, Survey

Outcome measures

Primary outcome

Primary Objective:

Among patients with symptomatic osteoarthritis of the knee(s) who are prescribed oral or topical analgesics for their symptoms, characterize over a 12-month follow-up period the clinical care and outcomes of patients who report inadequate pain relief (as defined by BPI *Average Pain* score) at baseline.

Secondary outcome

Secondary Objectives:

• Among patients with symptomatic knee OA who are prescribed oral or topical analgesics, characterize over a 12-month follow-up period the clinical care and outcomes of patients who report inadequate relief from joint stiffness or limitations in physical functioning (as defined by WOMAC Scores) at baseline.

• Among the entire study population of patients with symptomatic knee OA who are prescribed oral or topical analgesics (with and without adequate pain/symptom relief), describe or characterize at baseline and over the 12-month follow-up period:

• Demographic and clinical characteristics including comorbidities.

• Prescription and non-prescription medication and ancillary treatment used to treat symptoms of knee osteoarthritis

• Quality of life (QOL) related to knee osteoarthritis as measured by the SF-12.

• Pain as measured by items from the Brief Pain Inventory (BPI)

• Health resource utilization as measured by Healthcare Resource Utilization Questionnaire.

• Work productivity loss due to knee osteoarthritis as measured by the Work Productivity Activity Index (WPAI).

• Pain, joint stiffness and disability in the knee measured by the Western Ontario McMaster University Osteoarthritis Index (WOMAC) Questionnaire.

• Satisfaction with symptomatic treatment for knee OA as measured by treatment satisfaction questionnaire.

• Patient Response to Therapy as measured by the PGART (Patient Global Assessment of Response to Therapy) Questionnaire.

• Investigator Assessment of Response to Therapy as measured by the IGART (Investigator Global Assessment of Response to Therapy) Questionnaire.

Study description

Background summary

1.0 PROTOCOL SYNOPSIS
PRODUCT(s): None, This is an observational, prospective, single-cohort study and will include subjects being treated during usual clinical care with oral or topical analgesics used to relieve symptoms of osteoarthritis of the knee, according to standard medical guidelines or clinical practice standards of the investigating physician.

PROTOCOL TITLE: Survey of Osteoarthritis Real World Therapies (SORT)

US IND No: Not applicable

Clinical Phase: NA

OBJECTIVE:
Primary Objective:
Among patients with symptomatic osteoarthritis of the knee(s) who are prescribed oral or topical analgesics for their symptoms, characterize over a 12-month follow-up period the clinical care and outcomes of patients who report inadequate pain relief (as defined by BPI *Average Pain* score) at baseline.

Secondary Objectives:
• Among patients with symptomatic knee OA who are prescribed oral or topical analgesics, characterize over a 12-month follow-up period the clinical care and outcomes of patients who report inadequate relief from joint stiffness or limitations in physical functioning (as defined by WOMAC Scores) at baseline.

• Among the entire study population of patients with symptomatic knee OA who are prescribed oral or topical analgesics (with and without adequate pain/symptom relief), describe or characterize at baseline and over the 12-month follow-up period:

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HYPOTHESES
This is an observational study conducted for the purposes of descriptive analysis and hypothesis generation. No pre-specified hypothesis will be tested due to the exploratory nature of the study.

STUDY DESIGN AND DURATION:
This is an observational, prospective single-cohort study designed to characterize the course of clinical care and outcomes of subjects with symptomatic osteoarthritis of the knee(s) who are using oral or topical analgesics for their symptoms. The primary objective of the study is focused

upon the subset of all patients who report inadequate pain relief at entry into the study. A scheduled clinic visit will be performed at study enrollment and at Month 12, and subjects will be treated throughout the study according to usual clinical practice as determined by the attending physician. Any clinic visits that occur after Baseline and before Month 12 will be captured as an Unscheduled Visit. Treatment for knee OA, quality of life, pain, physical functioning related to knee OA, joint stiffness, treatment satisfaction, response to OA treatment, health care resource utilization and productivity will be measured by questionnaires completed at Months 0 (Baseline), 1, 3, 6, 9 and 12. Study entry and exit questionnaires will be performed during the scheduled clinic visits, and subjects will be provided with the questionnaires with instructions for completion and business reply envelopes for submission of those completed at Months 1, 3, 6 and 9.

This study will be conducted in seven countries (United Kingdom, France, Germany, Italy, Spain, the Netherlands and Portugal). Enrollment will be competitive within each country, with approximately 5 sites in each country (total approximately 35 sites), and a total of approximately 1400 subjects enrolled. Competitive enrollment means that within one particular country if the subject recruitment rate is lower than expected at one study site and higher than expected at another site, planned allocation numbers will be transferred from the site with low subject recruitment to a site with high recruitment. This will be done to ensure that subject enrollment within a given country is completed as planned. Additional participating countries and/or sites may be added during the study as required. Recruitment is expected to extend over a period of approximately 6 months, and each subject will be followed for twelve months.

SUBJECT SAMPLE:
This study will enroll male and female patients >= 50 years of age who have a clinical diagnosis of osteoarthritis of the knee(s). Subjects must be presently receiving prescribed (at the direction of a physician) oral or topical analgesics which commenced at least two weeks prior to enrollment.

DOSAGE / DOSAGE FORM, ROUTE and DOSE REGIMEN:
No investigational or approved medication will be provided. All subjects will be treated according to standard medical guidelines or clinical practice standards of the investigating physician.

SAFETY MEASURES:
This is an observational study conducted under conditions of normal clinical practice, and no therapeutic agents are provided under this protocol. Investigators will be responsible for adverse events reporting according to local, national, international and SPONSOR guidelines governing AE reporting.

DATA ANALYSIS:

PRIMARY ANALYSIS
The primary analysis for this study will be a general descriptive characterization of the clinical care of subjects with osteoarthritis of the knee(s). The primary objective of the study is focused upon the subset of all patients who do not have adequate pain relief with their OA treatment at entry into the study.

The analysis will include descriptive characterizations of the following parameters at baseline, at Months 1, 3, 6, 9 and 12 and any unscheduled visit:
• Subject demographic and defined clinical characteristics at study entry, including comorbidities
• Prescription and non-prescription, and other ancillary/complementary medications used for treatment of knee OA
o Use of nonprescription, herbal, and other ancillary/complementary medications used for the treatment of symptomatic knee osteoarthritis during the observation period
o Non-medicinal therapeutic interventions including diathermy, transcutaneous electrical nerve stimulation, topical applications, acupuncture, physical therapy, massage and surgery
• Quality of life (QOL) related to knee OA as measured by the SF-12.
• Pain as measured by items from the Brief Pain Inventory (BPI).
• Health resource utilization as measured by Healthcare Resource Utilization Questionnaire.
• Work productivity loss due to knee osteoarthritis as measured by the Work Productivity Activity Index (WPAI).
• Pain, joint stiffness and disability in the knee measured by the Western Ontario McMaster University Osteoarthritis Index (WOMAC) Questionnaire.
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The analysis will also evaluate longitudinally throughout the duration of study the following:
• Patterns of change in prescription treatment during the period of observation including
o Prescription treatment for knee osteoarthritis
o Time to discontinuation of baseline analgesic medication
o Time to commencement of another analgesic medication
o Change in dose and/or frequency of baseline or new analgesic treatments
o Time to commencement of complementary medication
o Time to discontinuation of complementary medication
o Change in dose and/or frequency of complementary medication
• Use of nonprescription, herbal, and other ancillary/complementary medications used for the treatment of symptomatic knee osteoarthritis during the

observation period
• Non-medicinal therapeutic interventions including diathermy, transcutaneous electrical nerve stimulation, topical applications, acupuncture, physical therapy, massage and surgery
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All data will be summarized using standard descriptive statistics (numerical variables: n, mean, median, standard deviation, minimum and maximum; categorical variables: n, percent). Time to event variables will be summarized using Kaplan-Meier estimates.

The incidence and intensity of adverse events will be tabulated for all subjects enrolled, grouped by MedDRA SOC and Preferred Terms . The incidence of the use concomitant medications will be summarized similarly, grouped by WHO ATC Classes and Preferred Terms.

All descriptive analyses will be performed overall ("All Countries") and by country (*Country Specific*). Interpretation of the findings will be based on the "All Countries" results unless there is evidence of important variation in the "Country Specific" analysis. Judgement as to whether important variation is seen will be based on both reasoned judgement and p-values associated with the observed differences. In general, all analytical results will be interpreted descriptively, as hypothesis-generating rather than confirmatory, and will be presented as such in any dissemination of the study results. Differences and ratio measures comparing groups will be presented with 95% confidence intervals. P-value thresholds may be used in the construction multivariate regression model for purposes of deciding which variables to include or drop from the model.

Study objective

OBJECTIVE:
Primary Objective:
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prescribed oral or topical analgesics for their symptoms, characterize over a 12-month follow-up period the clinical care and outcomes of patients who report inadequate pain relief (as defined by BPI *Average Pain* score) at baseline.

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STUDY DESIGN AND DURATION:
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Study burden and risks

No risks; the patient will receive regular treatment for his osteoarthritis of the knee and will fill out on 6 timepoints osteoarthritis questionaires. Patient will be filling out these questionaires, which may take up to half an hour per occasion. Total amount of time will be 3-4 hours during the participation in this trial.

Patients will not directly benefit, however from filling out the questionaires the patient may be obtaining a better understanding in the development of his osteoarthritis of the knee. From the knowledge gained in this trial patients may benefit in the future.

Contacts

Public
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NL
Scientific
Syreon Corporation

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NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

INCLUSION CRITERIA
1. Male or female subjects who are at least 50 years of age at the time of enrollment.
2. Subjects with a clinical diagnosis of primary osteoarthritis of the knee(s) .
3. Subjects who are presently receiving prescribed oral or topical analgesics for a minimum duration of two weeks prior to enrollment.
4. Subjects who have provided informed consent and are willing and able to follow the protocol.

Exclusion criteria

EXCLUSION CRITERIA
1. Subjects with any arthritis other than primary osteoarthritis.
2. Subjects who are or have been treated with DMARDS, methotrexate or biologics.
3. Subjects considered by the investigator to be unwilling or unable to complete the study or unable to comprehend or complete the study questionnaires.
4. Subjects who are unwilling to comply with the protocol or who are unable to complete the questionnaires.
5. Subjects with active litigation and compensation issues including disability dispute cases with government.
6. Subjects with subtotal or total joint replacement in the affected knee.
7. Subjects with chronic severe pain of other causes that in the opinion of the investigator may require long-term analgesia or confound the present study.
8. Subjects currently enrolled in a clinical trial or who have participated in a clinical trial

within the past 30 days.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-02-2011
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	08-02-2011
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	26-09-2011
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	25-10-2011
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	01-11-2012
Application type:	Amendment

Review commission: METC Twente (Enschede)

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
ClinicalTrials.gov	NCT01294696
CCMO	NL34197.044.10