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Evaluation Of The Clinical Benefit Obtained In Patients With Knee And/Or Hip Osteoarthritis After A Proactive Intervention On The Primary Care Physician

Submission date
04/02/2010

Recruitment status
No longer recruiting

Registration date
19/02/2010

Overall study status
Completed

Last Edited
22/02/2010

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Study of the clinical benefit and quality of life perception in patients with osteoarthritis of the hip and the knee. Evaluation based on a proactive follow-up intervention made by primary care physicians. Experimental open, randomized and controlled study.

Acronym
ARTRO-pro_AP

Study objectives
Despite the availability of evidence-based guidelines for the management of asymptomatic chronic diseases such as osteoarthritis, physicians often do not initiate, intensify or optimize therapy when indicated, so that patients are not treated effectively. This phenomenon is known as clinical inertia. The main objective of this study was to evaluate whether an intervention on primary care physicians to avoid clinical inertia, could improve the perception of pain, functionality and quality of life in patients with hip and/or knee osteoarthritis (OA).

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Ethical Committee of Hospital Universitario 12 de Octubre approved on August 1st, 2007. Notification was sent to the Spanish Agency of Medicines and Health Products (Agencia Española de Medicamentos y Productos Sanitarios [AEMPS]) on November 20th, 2007.

Study design
Multicentre prospective cluster randomised controlled parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Not Specified

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
Hip and Knee Arthritis

Interventions
Clusters of primary care physicians working at the same healthcare centre for more than 6 months were randomly assigned to 1 of 2 study groups.
1. Group 1 (Proactive Intervention): Physicians in this group received a 45-60 minute training session on the latest European League Against Rheumatism (EULAR) recommendations on OA management, therapeutic goals, motivational techniques, and the Visual Analogue Scale (VAS), Western Ontario and McMaster Universities (WOMAC) and Short Form-12 (SF-12) questionnaires.
2. Group 2 (Control): Physicians in this group received only a brief description of the study.
Each physician includes the first three patients with knee and/or hip OA who fulfil the eligibility criteria. Both groups were given the same Case Report Forms. All patients were scheduled for two visits (Visit 1 and Visit 2), six-months apart, during which a complete medical evaluation was carried out and VAS, WOMAC and SF-12 questionnaires were completed.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Evaluation of the clinical benefit of an educational intervention for primary care physicians, proposing a proactive approach to care (defined as a focus on updated treatment recommendations) in patients with arthritis. The primary outcome was measured by comparing results from visit 1 with those of visit 2.

Secondary outcome measures
1. Clinical characteristics, and progression of pain and functional capacity, in patients with knee and/or hip OA in Primary Care practice
2. identification of additional factors related with clinical inertia that, when modified, could result in clinical benefit for the patient
3. Description of characteristics of usual clinical practice carried out by primary care physicians

Overall study start date
01/10/2007

Completion date
30/06/2008

Eligibility

Key inclusion criteria
Physicians:
1. Belong to reselected Primary Care health centre
2. Have a daily clinical activity
3. Able to demonstrate a permanency up to 9 months in a clinical job
4. Commitment to follow all study criteria and recommendations
Patients:

1. Known diagnosis of hip and/or knee osteoarthritis fulfilling American College of Rheumatology (ACR) criteria.
2. Selected by physician (study subject) and gives informed consent to participate in this trial.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
1,925 Primary Care Physicians

Key exclusion criteria
Physicians:
1. Unable to ensure job stability at Primary Care health centre over 9 months
2. Does not accept study criteria and recommendations
3. Already involved in improvement effort programs regarding clinical support for patients affected by joint disease
Patients:
1. Clinical antecedents of actual arthritic disease with prosthesis implanted
2. Arthritic disease involving exclusively or predominantly the spine (all locations) or upper limbs
3. Severe concomitant pathology with a short term life expectancy
4. Existence of non-arthritic rheumatic condition (fibromyalgia, rheumatoid arthritis, psoriasis, collagen diseases)
5. Psychological or sensorial impairment that prevents study participation
6. Existence of any absolute contraindication for anti-arthritic medications (Non-Steroidal Anti-Inflammatory Drugs [NSAIDs], etc.)
7. Does not wish to participate
8. Potential surgical intervention (next 6 months)
9. Additionally, any patients considered by his/her physician to be clinically inappropriate for participation and clinical data collection in this study

Date of first enrolment
01/10/2007

Date of final enrolment
30/06/2008

Locations

Countries of recruitment
Spain

Study participating centre

Hospital Universitario 12 de Octubre
Madrid
Spain
28041

Sponsor information

Organisation
Spanish Society of Family Medicine and Community (Sociedad Española de Medicina de Familia y Comunitaria [SEMFYC]) (Spain)

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Sponsor type
Government

ROR
https://ror.org/01hn8xm90

Funder(s)

Funder type
Industry

Funder Name
Merck, Sharp & Dohme de España S.A. (Spain) - educational grant

Funder Name
Family and Community Spanish Medical Society (SEMFyC) (Spain)

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