

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

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<b>Registration date</b> 19/02/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 22/02/2010	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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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)

### **Sponsor details**

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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