

# Efficacy of the treatment with a COX-2 specific inhibitor celecoxib in osteoarthritic patients

<b>Submission date</b> 06/07/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 08/07/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 02/10/2008	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Javier Santillana

**Contact details**  
Orthopaedic Department  
Hospital de Tortosa Virgen de la Cinta  
Esplanetes 47  
Tortosa - Tarragona  
Spain  
43500  
+34 977519133  
jsanmher@eresmas.com

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N/A

# Study information

## Scientific Title

## Acronym

COXOA

## Study objectives

Our hypothesis is that celecoxib could have a specific antiinflammatory profile to that of a classic antiinflammatory treatment on patients with knee osteoarthritis (OA).

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Not provided at time of registration

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied

Advanced osteoarthritis

## Interventions

Comparison of celecoxib treatment versus aceclofenac treatment

## Intervention Type

Drug

## Phase

Not Specified

## Drug/device/biological/vaccine name(s)

Celecoxib and aceclofenac

**Primary outcome measure**

Synovial inflammation markers on the synovial membrane of osteoarthritis patients

**Secondary outcome measures**

Effect on Western Ontario McMaster Universities Osteoarthritis (WOMAC) index

**Overall study start date**

12/02/2002

**Completion date**

12/02/2003

## Eligibility

**Key inclusion criteria**

Patients with clinical and radiological evidence of knee OA who met the American Rheumatism Association criteria for functional classes III or IV, who were scheduled for total knee replacement and who accepted to be treated with an antiinflammatory drug.

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

30

**Key exclusion criteria**

Pregnancy, gastrointestinal pathology, kidney or hepatic insufficiency, diabetes, cardiovascular disease, oncologic patients.

**Date of first enrolment**

12/02/2002

**Date of final enrolment**

12/02/2003

## Locations

**Countries of recruitment**

Spain

**Study participating centre**

**Orthopaedic Department**  
Tortosa - Tarragona  
Spain  
43500

## **Sponsor information**

### **Organisation**

Hospital de Tortosa Virgen de la Cinta (Spain)

### **Sponsor details**

Javier Santillana  
Orthopaedic Department  
Hospital de Tortosa Virgen de la Cinta  
Esplanetes 47  
Tortosa - Tarragona  
Spain  
43500  
+34 977519133  
jsanmher@eresmas.com

### **Sponsor type**

Hospital/treatment centre

### **ROR**

<https://ror.org/046sqxa62>

## **Funder(s)**

### **Funder type**

Industry

### **Funder Name**

Mapfre Medicina Foundation (grant 2003), Spanish Ministry of Education (SAF 08/0379), Fondo de Investigaciones Sanitarias (CP03/00011), Pfizer 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

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/12/2008		Yes	No