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

Submission date	Recruitment status	[ ] Prospectively registered
06/07/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
08/07/2005	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
02/10/2008	Musculoskeletal Diseases	

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

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
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43500

Sponsor information

Organisation
Hospital de Tortosa Virgen de la Cinta (Spain)

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/046sqxa62

Funder(s)

Funder type
Industry

Funder Name
Mapfre Medicina Foundation (grant 2003), Spanish Ministery 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?
Results article	results	01/12/2008		Yes	No