

# Protocol to investigate the effect of cyclo-oxygenase (COX)-2 inhibition on reducing central sensitisation of pain in osteoarthritis

<b>Submission date</b> 28/07/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 30/09/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 17/04/2019	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<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 Ernest Choy

### Contact details

Weston Education Centre  
10 Cutcombe Road  
London  
United Kingdom  
SE5 9RJ  
+44 (0)207 848 5206  
kch-tr.kms-ctu@nhs.net

## Additional identifiers

### Clinical Trials Information System (CTIS)

2006-000395-32

### Protocol serial number

N/A

## Study information

**Scientific Title**

Protocol to investigate the effect of cyclo-oxygenase (COX)-2 inhibition on reducing central sensitisation of pain in osteoarthritis

**Study objectives**

This study aims to assess whether cyclo-oxygenase (COX)-2 selective inhibition by etoricoxib reduces central sensitisation of pain in patients with chronic osteoarthritis (OA) using functional magnetic resonance imaging (fMRI) scan.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

St Thomas' Hospital Research Ethics Committee. Date of approval: 23/03/2006

**Study design**

Non-randomised controlled trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

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

Osteoarthritis

**Interventions**

16 patients will be recruited from the Rheumatology Outpatient Clinic of King's College Hospital. 16 healthy controls will be recruited from the staff and student population at King's College London (32 participants in total).

Interventions: Etoricoxib (oral) 60 mg daily for 2 weeks vs no treatment

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome(s)**

1. Pressure pain thresholds (PPTs) will be determined using a pressure algometer. Patients will be asked to indicate the site of ongoing pain on a mannequin. This site and the homologous contralateral site will be marked with a pen and noted in the patient record. The pressure pain level will be assessed twice at each site (rate of stimulus increase 50 kPa; probe area 1 cm<sup>2</sup>) and the average of two perception levels will be calculated as the individual PPT for that site.  
2. Functional MRI (fMRI) will be used to assess brain responses to a standardised pain provocation produced by pressure delivered to a non fibromyalgia syndrome (FMS) pressure point of the knee. The fMRI evaluation will involve multiple 8 min scans using an event-related design. Pressure stimuli of 2.5 seconds duration will be delivered to the right knee at random

intervals varying between 10 and 20 seconds. This will then be repeated for the left knee. The control group will have only one scan.

Assessments will be carried out at baseline and after 2 weeks of treatment with etoricoxib for OA patients. Healthy controls will only complete baseline assessments.

**Key secondary outcome(s))**

1. Mechanoreceptive function
2. Sensitivity to stimulus invoked pain

Assessments will be carried out at baseline and after 2 weeks of treatment with etoricoxib for OA patients. Healthy controls will only complete baseline assessments.

**Completion date**

01/03/2009

## **Eligibility**

**Key inclusion criteria**

For all participants:

1. Both males and females, age >18 years old
2. Those who are right handed
3. Signed informed consent

For participants with OA:

1. Patients with ACR criteria defined OA of the knee
2. Radiological OA
3. Patients who have been suffering from pain for more than 1 year

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. History of hypersensitivity to the active substance or to any of the excipients
2. Active peptic ulceration or active gastro-intestinal (GI) bleeding
3. Patients who have experienced bronchospasm, acute rhinitis, nasal polyps, angioneurotic oedema, urticaria, or allergic-type reactions after taking acetylsalicylic acid or non-steroidal anti-inflammatory drugs (NSAIDs) including COX-2 inhibitors

4. Pregnancy and lactation
5. Severe hepatic dysfunction (serum albumin <25 g/l or Child-Pugh score ≥10)
6. Estimated renal creatinine clearance <30 ml/min
7. Inflammatory bowel disease
8. Congestive heart failure (New York Heart Association [NYHA] II-IV)
9. Patients with hypertension whose blood pressure has not been adequately controlled

**Date of first enrolment**

01/09/2008

**Date of final enrolment**

01/03/2009

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Weston Education Centre**

London

United Kingdom

SE5 9RJ

## Sponsor information

**Organisation**

Kings College London (UK)

**ROR**

<https://ror.org/0220mzb33>

## Funder(s)

**Funder type**

Industry

**Funder Name**

Merck Sharp & Dohme Ltd (MSD) (UK)

# Results and Publications

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="#">Basic results</a>				No	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes