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

Submission date
28/07/2008

Recruitment status
No longer recruiting

Registration date
30/09/2008

Overall study status
Completed

Last Edited
17/04/2019

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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 cm2) 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?
Basic results				No	No