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Effect of valdecoxib pretreatment on pain and secondary hyperalgesia associated with the heat /capsaicin model in healthy volunteers

Submission date 29/11/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/11/2005	**Overall study status** Completed	
Last Edited 03/10/2017	**Condition category** Signs and Symptoms	

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
NCT00260325

Secondary identifying numbers
N/A

Study information

Scientific Title
Effect of valdecoxib pretreatment on pain and secondary hyperalgesia associated with the heat /capsaicin model in healthy volunteers

Study objectives
Selective COX-2 inhibitors significantly attenuate central sensitization and decrease secondary hyperalgesia: a randomised clinical trial

Ethics approval required
Old ethics approval format

Ethics approval(s)
IRB approval at Penn State Hershey Medical Center

Study design
Prospective, double blind, randomized, cross-over

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Interventions
Administration of single dose 40 mg valdecoxib or placebo orally (PO).
Measurement of heat/cold pain threshold and area of heat/capsaicin-induced hyperalgesia.

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome measure
Area of secondary hyperalgesia

Secondary outcome measures
Pain threshold for cold/heat pain

Overall study start date
01/01/2004

Completion date
01/01/2006

Eligibility

Key inclusion criteria
Healthy volunteers, both genders

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
40

Key exclusion criteria
Pregnancy, known allergy to COX-2 inhibitors, current infection or treatment with analgesics

Date of first enrolment
01/01/2004

Date of final enrolment
01/01/2006

Locations

Countries of recruitment
United States of America

Study participating centre

Penn State Hershey Medical Ctr
Dept. Anesthesiology
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United States of America
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Sponsor information

Organisation
Pfizer Inc. (USA)

Sponsor details
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Sponsor type
Industry

ROR
https://ror.org/01xdqrp08

Funder(s)

Funder type
Industry

Funder Name
Independent Investigator Grant from Pfizer Inc.

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	10/03/2006		Yes	No