ISRCTN05282752 https://doi.org/10.1186/ISRCTN05282752

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

Registration date
30/11/2005

Overall study status
Completed

Last Edited
03/10/2017

Condition category
Signs and Symptoms

[_] 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

ClinicalTrials.gov (NCT)
NCT00260325

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

Primary study design
Interventional

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

Study type(s)
Treatment

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(s)
Area of secondary hyperalgesia

Key secondary outcome(s)
Pain threshold for cold/heat pain

Completion date
01/01/2006

Eligibility

Key inclusion criteria
Healthy volunteers, both genders

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
Hershey
United States of America
PA 17036

Sponsor information

Organisation
Pfizer Inc. (USA)

ROR
https://ror.org/01xdqrp08

Funder(s)

Funder type
Industry

Funder Name
Independent Investigator Grant from Pfizer Inc.

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?
Results article	results	10/03/2006		Yes	No