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A comparison of the effects of rofecoxib and diclofenac on the PFA-100, a laboratory based indicator of platelet function, in a post-operative neurosurgical population

Submission date
12/09/2003

Registration date
12/09/2003

Last Edited
19/07/2012

Recruitment status
Stopped

Overall study status
Stopped

Condition category
Haematological Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

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
N0263111551

Study information

Scientific Title

Study objectives
Does rofecoxib, a non-steroidal COX II inhibitor analgesic, cause less platelet dysfunction than diclofenac, a standard non-steroidal COX I inhibitor, in post-operative neurosurgical patients when used as analgesic adjuncts?

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)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Platelet dysfunction

Interventions
1. Rofecoxib
2. Diclofenac

This trial was stopped in September 2003 due to participant recruitment issues.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Rofecoxib, diclofenac

Primary outcome measure
Assessment of comparative effects of COX I/COX II inhibitors on platelet function using the platelet function analyser, the PFA-100, on blood samples taken from the participants.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/06/2002

Completion date
01/09/2004

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
30 Patients from Neurosurgery/NSITU.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
30

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/06/2002

Date of final enrolment
01/09/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The National Hospital for Neurology and Neurosurgery
London
United Kingdom
WC1N 3BG

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University College London Hospitals NHS Trust (UK)

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