# 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	Recruitment status	<ul><li>Prospectively registered</li></ul>
12/09/2003	Stopped	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
12/09/2003	Stopped	☐ Results
Last Edited	Condition category	Individual participant data
19/07/2012	Haematological Disorders	☐ Record updated in last year

# Plain English summary of protocol

Not provided at time of registration

# **Contact information**

# Type(s)

Scientific

#### Contact name

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#### Contact details

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# Additional identifiers

# Protocol serial number

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

# Study type(s)

Treatment

# 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(s)

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.

# Key secondary outcome(s))

Not provided at time of registration

# 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** 

# Healthy volunteers allowed

No

# Age group

**Not Specified** 

#### Sex

**Not Specified** 

# 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

United Kingdom

England

# Study participating centre The National Hospital for Neurology and Neurosurgery London

United Kingdom WC1N 3BG

# Sponsor information

# Funder(s)

# Funder type

Hospital/treatment centre

#### Funder Name

University College London Hospitals NHS Trust (UK)

# **Results and Publications**

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

Not provided at time of registration