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The cerebrospinal fluid (CSF) pharmacokinetics of a single pre-operative intravenous bolus dose of diclofenac (Dyloject®) in comparison to diclofenac infusion (Voltarol®)

Submission date 23/12/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 12/02/2009	**Overall study status** Completed	
Last Edited 09/06/2016	**Condition category** Surgery	

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
BLT-Dylo-07/01

Study information

Scientific Title
The cerebrospinal fluid (CSF) pharmacokinetics of a single pre-operative intravenous bolus dose of diclofenac (Dyloject®) in comparison to diclofenac infusion (Voltarol®): a prospective open-label randomised single-centre phase IV study

Study objectives
Dyloject®, a novel injectable diclofenac bolus is ideally suited for peri-operative anti-inflammatory analgesic use, and in view of the high peak plasma concentration following rapid intravenous administration may facilitate greater penetration of the central nervous system (CNS) and hence exert additional beneficial central actions.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East Regional Ethics Committee approval decision awaiting as of 14th January 2009

Study design
Prospective open-label randomised single-centre phase IV study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Peri-operative anti-inflammatory analgesia

Interventions
Dyloject® (75 mg) single intravenous bolus or Voltarol® ampoules (75 mg) single intravenous infusion will be given pre-operatively prior to spinal anaesthesia for surgery and cerebrospinal fluid sampling.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Diclofenac (Dyloject®, Voltarol®)

Primary outcome measure
Characterisation of the CSF diclofenac kinetics following administration of intravenous Dyloject®. The patients will receive the drug at 65, 35 and 5 minutes prior to CSF sampling.

Secondary outcome measures
1. Characterise CSF PGE2 levels in the normal uninjured human with or without diclofenac
2. Establish baseline CSF and plasma prostaglandins and cytokine levels
3. Examine the relationship between CNS and plasma PGE2 levels
4. Establish proof of concept for further analyses: an optional continuation of this pilot study is proposed dependant on interim analysis of the first phase. This would entail a further 18 patients entering the study.

Overall study start date
05/02/2009

Completion date
05/08/2010

Eligibility

Key inclusion criteria
1. Male or female patients aged at least 18 years
2. Scheduled to undergo surgery performed under spinal anaesthesia
3. Patients must be inpatients
4. Patient has given written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20

Key exclusion criteria
1. History of bleeding diathesis or use of anticoagulant or antiplatelet agent
2. History of spinal or neurological disease (including raised intracranial pressure), or surgery contraindicating spinal anaesthesia
3. Use of aspirin within 72 hours prior to surgery
4. Use of other non-steroidal anti-inflammatory drugs (NSAIDs), paracetamol or steroids within 12 hours before surgery
5. Hypersensitivity to diclofenac or local anaesthetics
6. Aspartate aminotransferase (AST), alanine aminotransferase (ALT) or blood urea nitrogen (BUN) greater than 1.5 x the upper limit of the reference range, or creatinine greater than the upper limit of the reference range
7. Any other abnormal laboratory results considered clinically significant in relation to this study by the investigator
8. Presence of oliguria, anaemia, hypotension or hypovolaemia
9. Contraindications to NSAID/diclofenac
10. Patients who are unwilling or unable to conform to the protocol
11. Patients who have received an unlicensed drug less than 30 days prior to the study
12. Patients who have been previously admitted to the study
13. Pregnant or lactating females or females of child-bearing potential who are unwilling to undertake a pregnancy test (urinary beta-human chorionic gonadotropin [B-HCG])
14. A bloody tap (visible blood in CSF)
15. Patients with a hypersensitivity to the excipients hydroxypropylbetadex (HPßCD) or monothioglycerol
16. Operations with high risk of haemorrhage
17. Patients who are considered unsuitable by the responsible anaesthetist - for whom spinal anaesthesia is deemed to constitute an unacceptable, increased risk
18. Patients who are involved in existing research

Date of first enrolment
05/02/2009

Date of final enrolment
05/08/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
PARC
London
United Kingdom
EC1A 7BE

Sponsor information

Organisation
Barts and The London NHS Trust (UK)

Sponsor details
24 - 26 Walden Street
Whitechapel
London
England
United Kingdom
E1 2AB

Sponsor type
Hospital/treatment centre

Website
http://www.bartsandthelondon.org.uk/

ROR
https://ror.org/00b31g692

Funder(s)

Funder type
Industry

Funder Name
Javelin Pharmaceuticals UK Limited (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