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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

Registration date
12/02/2009

Last Edited
09/06/2016

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Surgery

[_] 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

Contact name
Dr Nilesh Randive

Contact details
PARC
Unit 11, First Floor Dominion House
59 Bartholomew Close
West Smithfield
London
United Kingdom
EC1A 7BE
-
drnilran@gmail.com

Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))

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.

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
United Kingdom

England

Study participating centre
PARC
London
United Kingdom
EC1A 7BE

Sponsor information

Organisation
Barts and The London NHS Trust (UK)

ROR
https://ror.org/00b31g692

Funder(s)

Funder type
Industry

Funder Name
Javelin Pharmaceuticals UK Limited (UK)

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes