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Measurement of the blood levels of the painkiller diclofenac in children following a single intravenous dose

Submission date 23/02/2010	**Recruitment status** Stopped	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 07/04/2010	**Overall study status** Stopped	
Last Edited 29/06/2017	**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

N/A

Study information

Scientific Title
A pharmacokinetic study of intravenous diclofenac (Dyloject®) in children undergoing routine surgery: an open-label, single-dose trial

Study objectives
To evaluate the standard pharmacokinetic parameters such as clearance and volume of distribution of Dyloject® when administered as a single intravenous bolus dose of 0.5 mg/kg.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Pan-Manchester R&D committee - approval pending

Study design
Open-label single-dose pharmacokinetic trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Pharmacokinetic study in children

Interventions
Children will be starved according to the UK National Paediatric Starvation Guideline produced by the Association of Paediatric Anaesthetists of GB & Ireland in conjunction with The Royal College of Nursing. The guideline stipulates 2 hours for clear fluids and six hours for solids/food. 25 healthy children aged 2 to 8 years undergoing elective surgery will receive a single intravenous dose of diclofenac (trade name Dyloject®) 0.5 mg/kg on induction of anaesthesia. Seven 1.5 ml blood samples will be collected from each child at 2, 5, 15, 60, 120, 240 and 360 minutes after the administration of the drug through a dedicated intravenous cannula. Routine postoperative observations of temperature, pulse, blood pressure and oxygen saturation will be performed during the study period of 6 hours and beyond that as indicated by the type of surgery and postoperative care required.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Diclofenac

Primary outcome measure
Plasma diclofenac assays

Secondary outcome measures
Measuring decaying plasma concentrations to estimate ancillary parameters such as Cmax, Tmax, UAC and T1/2

Overall study start date
01/06/2010

Completion date
01/06/2011

Reason abandoned (if study stopped)
Objectives no longer viable

Eligibility

Key inclusion criteria
Children aged 2 to 8 years undergoing routine surgery including ear, nose and throat (ENT), orthopaedic, urological and general

Participant type(s)
Patient

Age group
Child

Lower age limit
2 Years

Upper age limit
8 Years

Sex
Both

Target number of participants
25

Key exclusion criteria

1. Previous allergic reaction to nonsteriodal anti-inflammatory drugs (NSAIDs)
2. Known bleeding tendency
3. Administration of a NSAID within the past 24 hours
4. History of liver disease, abnormal renal function and gastrointestinal bleeding
5. Children with special needs in view of consent issues

Date of first enrolment
01/06/2010

Date of final enrolment
01/06/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Manchester Children's Hospital
Manchetser
United Kingdom
M13 9WL

Sponsor information

Organisation
Central Manchester Foundation Trust (CMFT) (UK)

Sponsor details
CMFT Headquarters
Oxford Road
Manchester
England
United Kingdom
M13 9WL

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00he80998

Funder(s)

Funder type
Industry

Funder Name
TherabelPharma NV (Netherlands)

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