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

	[X] Prospectively registered
Stopped	☐ Protocol
Overall study status	Statistical analysis plan
Stopped	☐ Results
Condition category	☐ Individual participant data
	Record updated in last year
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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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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 planNot provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration