

The efficacy of non-steroidal anti-inflammatory drugs and their effect on renal function in small infants following minor surgery

Submission date 12/09/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 05/12/2014	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

The efficacy of non steroidal anti-inflammatory drugs and their effect on renal function in small infants following minor surgery

Study objectives

The primary objective is to establish the efficacy of non-steroidal anti-inflammatory drugs (NSAIDs) compared with paracetamol in small infants following minor surgery.

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Urological and Genital Diseases: Renal function

Interventions

Random allocation to (A) Non-steroidal anti-inflammatory drugs (B) Paracetamol.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Non-steroidal anti-inflammatory drugs, paracetamol

Primary outcome measure

1. Pain scores
2. Time to supplementary analgesia
3. Total supplementary analgesia
4. Changes in renal function

Secondary outcome measures

Not provided at time of registration

Overall study start date

10/07/2003

Completion date

10/07/2005

Eligibility

Key inclusion criteria

Infants who have undergone minor surgery

Participant type(s)

Patient

Age group

Child

Sex

Both

Target number of participants

Not provided at time of registration

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

10/07/2003

Date of final enrolment

10/07/2005

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Great Ormond Street Hospital
London
United Kingdom
WC1N 3JH

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
<http://www.doh.gov.uk>

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Great Ormond Street Hospital for Children

Alternative Name(s)
GOSH

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Funder Name

Institute of Child Health, University College London

Alternative Name(s)

UCL Great Ormond Street Institute of Child Health, GOS ICH

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

United Kingdom

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