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

Submission date	Recruitment status	[ ] Prospectively registered
12/09/2003	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/09/2003	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
05/12/2014	Urological and Genital Diseases	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N0012120214

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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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

Key secondary outcome(s)
Not provided at time of registration

Completion date
10/07/2005

Eligibility

Key inclusion criteria
Infants who have undergone minor surgery

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Sex
All

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
United Kingdom

England

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

Sponsor information

Organisation
Department of Health (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, UCL GOS ICH

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration