ISRCTN40177280 https://doi.org/10.1186/ISRCTN40177280

# Does oral diclofenac together with oral paracetamol affect gastric volumes and pH in children?

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|---|---|---|
| **Submission date**<br>30/09/2004 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol |
| **Registration date**<br>30/09/2004 | **Overall study status**<br>Completed | [_] Statistical analysis plan<br>[_] Results |
| **Last Edited**<br>07/09/2015 | **Condition category**<br>Surgery | [_] Individual participant data<br>[_] 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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
N0205128931

# Study information

### Scientific Title
Does oral diclofenac together with oral paracetamol affect gastric volumes and pH in children?

### Study objectives
Does diclofenac/paracetamol given orally pre-operatively together increase gastric contents when compared to paracetamol?

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Not provided at time of registration

### Study design
Randomised double-blind controlled trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Prevention

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

### Health condition(s) or problem(s) studied
Surgery: Pre-operative care

### Interventions
Diclofenac and paracetamol compared to paracetamol alone

### Intervention Type
Drug

### Phase
Not Applicable

### Drug/device/biological/vaccine name(s)
Diclofenac, paracetamol

### Primary outcome measure

Volume and pH of gastric contents at induction

### Secondary outcome measures
Not provided at time of registration

### Overall study start date
20/04/2003

### Completion date
20/02/2007

## Eligibility

### Key inclusion criteria
1. 50 children recruited from Royal London Hospital paediatric wards, aged 2-15 years
2. Elective surgery
3. American Society of Anesthesiologists (ASA) I/II

### Participant type(s)
Patient

### Age group
Child

### Lower age limit
2 Years

### Upper age limit
15 Years

### Sex
Both

### Target number of participants
50

### Key exclusion criteria
Does not meet inclusion criteria

### Date of first enrolment
20/04/2003

### Date of final enrolment
20/02/2007

## Locations

### Countries of recruitment
England

United Kingdom

**Study participating centre**
**Royal London Hospital**
London
United Kingdom
E1 1BB

# Sponsor information

**Organisation**
Department of Health

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

**Sponsor type**
Government

**Website**
http://www.dh.gov.uk/Home/fs/en

# Funder(s)

**Funder type**
Government

**Funder Name**
Barts and The London NHS Trust (UK)

# 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