

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

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| Submission date 30/09/2004 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| | | <input type="checkbox"/> Protocol |
| Registration date 30/09/2004 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan |
| | | <input type="checkbox"/> Results |
| Last Edited 07/09/2015 | Condition category Surgery | <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

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Additional identifiers

Protocol serial number
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

Study type(s)

Prevention

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(s)

Volume and pH of gastric contents at induction

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

2 years

Upper age limit

15 years

Sex

All

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**

United Kingdom

England

Study participating centre

Royal London Hospital

London

United Kingdom

E1 1BB

Sponsor information**Organisation**

Department of Health

Funder(s)

Funder type

Government

Funder Name

Barts and The London NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration