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

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

Submission date 30/09/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 30/09/2004	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 07/09/2015	**Condition category** Surgery	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr S Bhatia

Contact details
Anaesthetic Dept
Royal London Hospital
Whitechapel
London
United Kingdom
E1 1BB

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