ISRCTN89982548 https://doi.org/10.1186/ISRCTN89982548

Does the administration of intravenous (IV) fluids intra-operatively reduce the incidence of post-operative nausea and vomiting in children undergoing day-surgery?

Submission date
30/09/2004

Registration date
30/09/2004

Last Edited
24/09/2013

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] 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

N0205128954

Study information

Scientific Title

Study objectives
Does the administration of IV fluids intra-operatively reduce the incidence of post-operative nausea and vomiting in children undergoing day-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)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Nausea and vomiting; surgery

Interventions
Randomised double blind controlled trial
Group 1: Children will receive 20 ml/kg of IV compound sodium lactate solution intra-operatively
Group 2: Children will receive no intravenous fluid intra-operatively

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
Incidence of nausea and vomiting

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/09/2003

Completion date
01/06/2007

Eligibility

Key inclusion criteria
300 children between 2 and 12 years

Participant type(s)
Patient

Age group
Child

Lower age limit
2 Years

Upper age limit
12 Years

Sex
Both

Target number of participants
300

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
01/09/2003

Date of final enrolment
01/06/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Anaesthetic Dept
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