Randomised controlled study of fundoplication or medical treatment for gastro-oesophageal reflux in children

Submission date	Recruitment status	Prospectively registered
23/01/2004	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
23/01/2004	Completed	Results
Last Edited	Condition category	Individual participant data
16/06/2014	Digestive System	[] Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr David Lloyd

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Study objectives

To measure the effectiveness of fundoplication compared to medical managements in a randomised study of children with severe gastro-oesophageal reflux and thus develop management strategies for the appropriate and cost-effective treatment of children with gastro-oesophageal reflux.

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)

Not specified

Study type(s)

Not Specified

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

Digestive system diseases: Other digestive system disease

Interventions

Fundoplication vs medical management

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Body weight Z scores.

Secondary outcome measures

- 1. Continuing or recurrent gastro-oesophageal reflux
- 2. Complication rate after fundoplication, ECA on EGG
- 3. Validated quality of life score for patients and parents

Overall study start date

01/10/2000

Completion date

01/10/2003

Eligibility

Key inclusion criteria

Children aged less than 16 years with clinical evidence of gastro-oesophageal reflux. Phase One - 250 to 330. Phase Two - 115 to 125.

Participant type(s)

Patient

Age group

Child

Upper age limit

16 Years

Sex

Both

Target number of participants

455

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/10/2000

Date of final enrolment

01/10/2003

Locations

Countries of recruitment

England

Study participating centre
Royal Liverpool Children's Hospital NHS Trust
Liverpool
United Kingdom
L12 2AP

Sponsor information

Organisation

NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details

The Department of Health Richmond House 79 Whitehall London United Kingdom SW1A 2NL +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

http://www.doh.gov.uk

Funder(s)

Funder type

Government

Funder Name

NHS Executive North West (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