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

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

RHC22029

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

United Kingdom

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