

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

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Not Specified

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(s)

Body weight Z scores.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Child

Upper age limit

16 Years

Sex

All

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**

United Kingdom

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)

Funder(s)

Funder type

Government

Funder Name

NHS Executive North West (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration