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Efficacy of domperidone and/or omeprazole in the treatment of gastroesophageal reflux (GOR) in children - a comparative study

Submission date 30/09/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 30/09/2004	**Overall study status** Completed	
Last Edited 19/10/2016	**Condition category** Digestive System	

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
N0264130004

Study information

Scientific Title
Efficacy of domperidone and/or omeprazole in the treatment of gastroesophageal reflux (GOR) in children - a comparative study

Study objectives
The aim of this study is to document the efficacy of domperidone and/or omeprazole in neurologically normal and abnormal children found to have significant GOR on oesophageal pH monitoring.

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

Health condition(s) or problem(s) studied
Gastro-oesophageal reflux disease (GORD)

Interventions
Double blind placebo controlled prospective randomised controlled trial.
Randomised to:
A. Domperidone
B. Omeprazole
C. Combination of both

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Domperidone and omeprazole

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/03/2004

Completion date
01/05/2006

Eligibility

Key inclusion criteria
1. Children under 16
2. Reflux index >1

Participant type(s)
Patient

Age group
Child

Upper age limit
16 Years

Sex
Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/03/2004

Date of final enrolment
01/05/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
C/O Research & Effectiveness Department
Bristol
United Kingdom
BS2 8HW

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
United Bristol Healthcare NHS Trust

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