ISRCTN40276556 https://doi.org/10.1186/ISRCTN40276556

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
Registration date 30/09/2004	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 19/10/2016	**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

Contact name
Prof B K Sandhu

Contact details
C/O Research & Effectiveness Department
Level 1, The Old Building
Bristol Royal Infirmary
Malborough Street
Bristol
United Kingdom
BS2 8HW
+44 (0)117 928 3473
r&eoffice@ubht.swest.nhs.uk

Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Not Specified

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(s)
Not provided at time of registration

Key secondary outcome(s)
Not provided at time of registration

Completion date

01/05/2006

Eligibility

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

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Upper age limit
16 Years

Sex
Not Specified

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
United Kingdom

England

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

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Government

Funder Name
United Bristol Healthcare NHS Trust

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration