

Introduction of a community-based intervention for children with chronic constipation

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 29/04/2016	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

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Additional identifiers

Protocol serial number

N0045126756

Study information

Scientific Title

Introduction of a community-based intervention for children with chronic constipation

Study objectives

To assess the effect of the introduction of a primary care-based intervention for children with constipation compared to conventional hospital based management.

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

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Digestive System: Constipation

Interventions

A randomised controlled trial to compare a new nurse-led service with conventional hospital-based management for children with constipation.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

1. Clinical outcomes: remission and relapse of symptoms
2. Quality of life/patient and parental satisfaction
3. Cost benefits: on-going treatment, nurse contacts, out-patient visits and hospital admission

Key secondary outcome(s))

Not provided at time of registration

Completion date

31/03/2004

Eligibility

Key inclusion criteria

40 children aged 2-15 years with moderate to severe chronic constipation referred to gastroenterologists and general paediatricians in Birmingham Children's Hospital NHS Trust.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

2 years

Upper age limit

15 years

Sex

All

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/04/2003

Date of final enrolment

31/03/2004

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Birmingham Children's Hospital

Birmingham

United Kingdom

B4 6NH

Sponsor information**Organisation**

Department of Health

Funder(s)

Funder type

Government

Funder Name

Birmingham Children's Hospital NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration