

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

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| Submission date 30/09/2004 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 30/09/2004 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 29/04/2016 | Condition category Digestive System | <input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year |

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Susan Protheroe

Contact details
Birmingham Children's Hospital
Department of Gastroenterology
Steelhouse Lane
Birmingham
United Kingdom
B4 6NH
+44 (0)121 333 8720
Sue.protheroe@bch.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

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: 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 measure

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

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/04/2003

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

Age group

Child

Lower age limit

2 Years

Upper age limit

15 Years

Sex

Both

Target number of participants

40

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

England

United Kingdom

Study participating centre
Birmingham Children's Hospital
Birmingham
United Kingdom
B4 6NH

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
Birmingham Children's Hospital NHS Trust (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