

A randomised controlled trial of a pre-assessment clinic for paediatric general surgery day cases

Submission date 23/01/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 21/11/2019	Condition category Surgery	<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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

C/N/12/10-01-95/SMITH/D

Study information

Scientific Title

A randomised controlled trial of a pre-assessment clinic for paediatric general surgery day cases

Study objectives

The aim of this study was to compare two methods of preparing children and their parents for day case surgery. The two methods that were compared were providing information on the day of surgery (previous practice) versus providing information before admission at a pre-assessment clinic.

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)

Other

Participant information sheet

Health condition(s) or problem(s) studied

Paediatric surgery

Interventions

1. Information given on the day of admission
1. Information given at the preassessment clinic before admission

Intervention Type

Procedure/Surgery

Phase

Not Applicable

Primary outcome measure

1. Behavioural distress of the child around the time of the surgery
2. Behavioural disturbance of the child immediately after discharge from hospital and 4 months later
 - 2.1. Vernon post-hospital behaviour scale
 - 2.2. Rowe behavioural rating inventory
3. Likert-scale anxiety ratings of parent and child during the admission (completed by the parent prior to discharge)
4. Compliance of parents with home care instructions

Secondary outcome measures

Not provided at time of registration

Overall study start date

18/09/1995

Completion date

31/03/1999

Eligibility

Key inclusion criteria

Children listed for day case surgery at Bristol Children's Hospital.

Participant type(s)

Patient

Age group

Child

Sex

Both

Target number of participants

Not provided at time of registration

Key exclusion criteria

Does not match inclusion criteria

Date of first enrolment

18/09/1995

Date of final enrolment

31/03/1999

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
University of East Anglia
Norwich
United Kingdom
NR4 7TJ

Sponsor information

Organisation

NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details

The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

<http://www.doh.gov.uk>

Funder(s)

Funder type

Government

Funder Name

NHS Executive South West (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