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Randomised Trial of Rectal Prolapse Surgery

Submission date	Recruitment status	[_] Prospectively registered
02/06/2003	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/11/2003	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
02/05/2014	Urological and Genital Diseases	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.prosper.bham.ac.uk/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
PROSPER - PROlapse Surgery: PErineal or Rectopexy

Study objectives
Full thickness rectal prolapse is a profoundly disabling condition, occurring mainly in parous women. The pathogenesis is ill understood; curative treatment is exclusively surgical. The prevalence of the condition is not known. Amongst the 50% (154) of senior surgical members of the Association of Coloproctology responding to a questionnaire on the subject, the median number of prolapse operations performed annually was 6 (range 0-25). To make large-scale recruitment feasible, and to maximise the clinical relevance of the eventual findings, the National Rectal Prolapse Trial is designed to fit in with routine practice with a minimum of extra tests and investigations over those that would normally be required. About 1000 patients will be recruited into the trial over a 3 year period and followed for a minimum of 3 years.

A full thickness prolapse is the circumferential protrusion through the anus of all layers of the rectal wall. It is most common in young children and the elderly. The range of surgical methods available to correct the underlying anal sphincter or pelvic floor defects in a full thickness rectal prolapse poses the question about the choice of the best operation.

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

Health condition(s) or problem(s) studied
Full thickness rectal prolapse

Interventions
Given the uncertainty as to the best method of intervention and the lack of informative randomised evidence, a two-stage randomised, controlled clinical trial is proposed.
Eligibility for randomisation will be based on the 'uncertainty principle'; that is if a surgeon feels uncertain of the relative merits of the abdominal and perineal approach in a particular case, then randomisation can proceed between the abdominal and perineal approach.
Alternatively, the abdominal or perineal approach can be chosen if considered to be clearly indicated.

Randomisation two is then undertaken: if the abdominal approach is elected or allocated at randomisation, then randomisation is between Suture Rectopexy and Resection Rectopexy, if perineal, randomisation is between Delorme's and Altemeier's operations.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The primary measures of efficacy will be recurrence of rectal prolapse for randomisation 1 and bowel function for randomisation 2.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2001

Completion date
31/12/2007

Eligibility

Key inclusion criteria
Patients eligible for this study will be those with full thickness rectal prolapse.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
1000

Key exclusion criteria

Not provided at time of registration

Date of first enrolment
01/01/2001

Date of final enrolment
31/12/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St Mark's Hospital
Harrow
United Kingdom
HA1 3UJ

Sponsor information

Organisation
Clinical Trials Unit University of Birmingham (UK)

Sponsor details
Park Grange
1 Somerset Road
Edgbaston
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B15 2RR

Sponsor type
University/education

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Other

Funder Name
The NHS R&D funded Clinical Trials Unit at the University of Birmingham and The BUPA Foundation (The Medical Research Charity)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2013		Yes	No