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# Randomised Trial of Rectal Prolapse Surgery

**Submission date**
02/06/2003

**Recruitment status**
No longer recruiting

**Registration date**
20/11/2003

**Overall study status**
Completed

**Last Edited**
02/05/2014

**Condition category**
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

## 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

## Primary study design
Interventional

## Study design
Randomised controlled trial

## Study type(s)
Treatment

## 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(s)

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

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

### 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

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
All

### 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
United Kingdom

England

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

# Sponsor information

### Organisation
Clinical Trials Unit University of Birmingham (UK)

### 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

### 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 |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |