

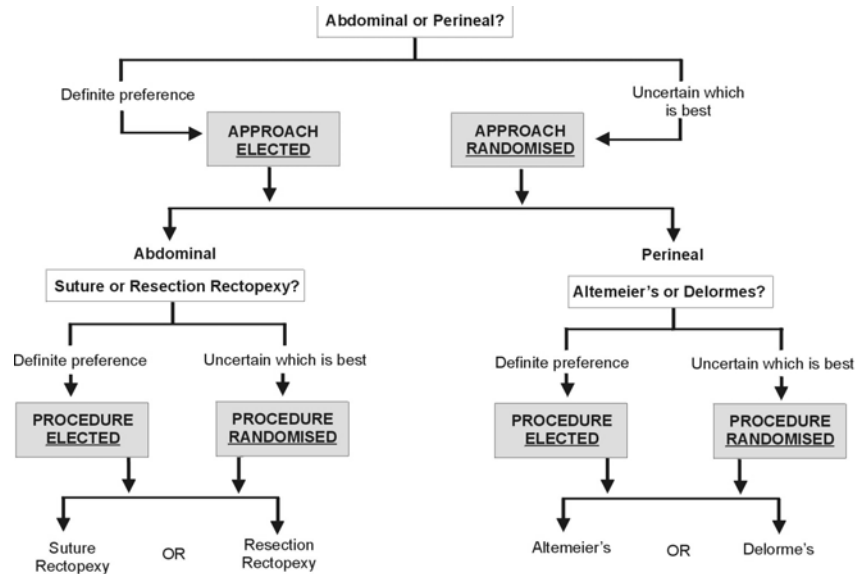
# PROSPER TRIAL SCHEMA

## ELIGIBILITY

- ◆ Patient has full thickness Rectal Prolapse.
- ◆ Patient has given informed consent.

## RANDOMISE IF UNCERTAIN

- ◆ The surgeon should consider whether it is appropriate for each patient with rectal prolapse to be randomised into the **PROSPER** trial. Randomisation should only take place when substantial uncertainty exists. If the surgeon considers, for whatever reason, that one or other choice of approach, and type of operation, is definitely indicated in a particular case the patient is not eligible to take part in the trial.



## OBTAINING PATIENT CONSENT

- ◆ At most centres, where pre-operative tests are not performed at a separate appointment, patients who agree to take part in the study should be asked to sign the consent form at the first clinic appointment. If they would prefer longer to decide they should be given a consent form to take away, sign, witness and return BY POST.
- ◆ However, in some centres, patients will have a second appointment for pre-operative tests and hence longer to consider participation.
- ◆ In either of these circumstances, there is a period of weeks between the randomisation and the operation and the patient should be told that they can change their mind about participation at any time. Confirmation of consent should be obtained on the usual pre-operative consent forms.
- ◆ Once initial consent has been gained randomisation can take place.

## TELEPHONE RANDOMISATION

- ◆ Prepare for telephone questions using the randomisation notepad (see Note A)
- ◆ Ring the randomisation service on 0800 953 0274 (toll-free in UK) or +44 (0)121 687 2319 from outside the UK.
- ◆ When all the relevant questions on the randomisation notepad have been answered, a treatment allocation and patient reference number will be given.

**Note A:** The person randomising will need to answer all questions on the randomisation notepad.

## FOLLOW-UP

- ◆ A routine post-operative visit at six weeks, and at one year and three years. Data collected will be recurrence of full-thickness rectal prolapse, continence (Kamm Score), and quality of life (EuroQoL).

### FOR RANDOMISATION TELEPHONE (TOLL FREE IN UK):

0800 953 0274 OR FAX +44 (0)121 415 9137 or +44 (0)121 415 9137 FROM OUTSIDE THE UK.

For administrative queries and trial supplies, contact the PROSPER Trial Office, University of Birmingham Clinical Trials Unit, Robert Aitken Institute, Edgbaston, Birmingham B15 2TT. Tel: 0121 415 9106 Fax: 0121 415 9136 Email: Prosper-Trial@contacts.bham.ac.uk