

Feasibility study for a randomised controlled trial evaluating the use of absorbable mesh, polydioxanone and polyglactin sutures for anterior and posterior vaginal wall prolapse repairs

Submission date

21/08/2005

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

15/09/2005

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

13/10/2009

Condition category

Urological and Genital Diseases

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Sabeena Allahdin

Contact details

26 Springdale Road Bieldside
Aberdeen
United Kingdom
AB15 9FA

Additional identifiers

Protocol serial number

Version 1 09 11 2004

Study information

Scientific Title

Acronym

IMPRESS: Is it Mesh or Suture for Prolapse Surgery Success

Study objectives

The use of absorbable mesh or not for primary prolapse surgery.

The choice of absorbable suture for primary prolapse surgery.

What will the work achieve?

We aim to answer the following questions:

1. Is absorbable mesh (polyglactin) effective in treatment of primary prolapse surgery?
2. Is polydioxanone (PDS) or polyglactin (Vicryl) a better suture material to use for primary prolapse surgery?
3. What are the effects of mesh and different suture material on short-term and long-term morbidity, recurrence of prolapse symptoms, and quality of life?
4. Is it feasible to mount a randomised controlled trial to answer these questions?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled 2x2 factorial design trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Prolapse

Interventions

A randomised controlled trial using a 2x2 factorial design of absorbable mesh compared with no mesh, and two types of sutures for anterior or posterior pelvic organ prolapse repair.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Recurrence of (or failure to cure) prolapse symptoms. One of the aims of the feasibility study is to test how best to assess these outcome measures and their inclusiveness.

Key secondary outcome(s)

1. Immediate and late postoperative morbidity
2. Recurrence of prolapse
3. Quality of life
4. Satisfaction with surgery and economic outcomes

Completion date

31/08/2005

Eligibility

Key inclusion criteria

All women admitted for primary pelvic organ prolapse surgery with grade 2 or more pelvic organ prolapse who are willing to participate in the trial. Women undergoing concurrent hysterectomy or continence procedures will also be eligible.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

Women with less than a grade 2 prolapse, those unwilling or unable to participate in the trial.

Date of first enrolment

15/05/2005

Date of final enrolment

31/08/2005

Locations

Countries of recruitment

United Kingdom

Scotland

Study participating centre

26 Springdale Road Bieldside

Aberdeen

United Kingdom

AB15 9FA

Sponsor information

Organisation

University of Aberdeen (UK)

ROR

<https://ror.org/016476m91>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Small departmental research fund

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	01/05/2008		Yes	No