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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	Recruitment status
21/08/2005	No longer recruiting
Registration date	**Overall study status**
15/09/2005	Completed
Last Edited	**Condition category**
13/10/2009	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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
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.

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

Overall study start date
15/05/2005

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

Age group
Adult

Sex
Female

Target number of participants
70

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
Scotland

United Kingdom

Study participating centre
26 Springdale Road Bieldside
Aberdeen
United Kingdom
AB15 9FA

Sponsor information

Organisation
University of Aberdeen (UK)

Sponsor details
Medical School
R&D Department
Foresterhill Annexe
Foresterhill Road
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Sponsor type
University/education

ROR
https://ror.org/016476m91

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Small departmental research fund

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	01/05/2008		Yes	No