

Surgery and physiotherapy for prolapse to avoid recurrence: a feasibility study

Submission date 01/06/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 02/08/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 02/06/2015	Condition category Urological and Genital Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Doreen McClurg

Contact details
Nursing, Midwifery and Allied Health Professions Research Unit
Glasgow Caledonian University
Buchanan House
Cowcaddens Road
Glasgow
United Kingdom
G4 0BA
+44 (0)141 331 8105
doreen.mcclurg@gcu.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PRF/09/1

Study information

Scientific Title

A two-group, single-blind, randomised controlled study to assess the feasibility of physiotherapy following surgery for prolapse to avoid recurrence

Acronym

SUPER

Study objectives

Women who undergo physiotherapy intervention following surgery for pelvic organ prolapse have short and long term symptom benefit when compared to those who do not have such an additional intervention

Ethics approval required

Old ethics approval format

Ethics approval(s)

Under application

Study design

Two-group single-blind feasibility study

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

Pelvic organ prolapse

Interventions

The control group will receive a lifestyle advice only

The treatment group will receive one pre-operative appointment, one post-operative appointment on the ward, followed by 6 appointments with a physiotherapist to encourage pelvic floor muscle training. Home exercises and lifestyle advice will also be provided.

Intervention Type

Behavioural

Primary outcome measure

1. Pelvic organ prolapse symptom score
 2. Organ prolapse quantification system
- All outcome measures will be completed pre-intervention and 6 and 12 months post-intervention

Secondary outcome measures

1. Incontinence Questionnaire Short Form (ICIQ-SF)
2. Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12)
3. Digital assessment of pelvic floor muscles
4. SF-12

All outcome measures will be completed pre-intervention and 6 and 12 months post-intervention

Overall study start date

01/06/2010

Completion date

31/05/2012

Eligibility

Key inclusion criteria

Women who undergo surgery for pelvic organ prolapse and are able to attend for pre and post operative follow-ups

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

30

Key exclusion criteria

Women who have undergone individual Pelvic Floor Muscle Training (PFMT) during the previous 3 years or have undergone surgery for gynaecological cancer

Date of first enrolment

01/06/2010

Date of final enrolment

31/05/2012

Locations

Countries of recruitment

Scotland

United Kingdom

Study participating centre
Glasgow Caledonian University
Glasgow
United Kingdom
G4 0BA

Sponsor information

Organisation
Physiotherapy Research Foundation (UK)

Sponsor details
The Chartered Society of Physiotherapy
14 Bedford Row
London
United Kingdom
WC1R 4ED
-
attew@csp.org.uk

Sponsor type
Charity

ROR
<https://ror.org/04sn78z72>

Funder(s)

Funder type
Charity

Funder Name
Physiotherapy Research Foundation (UK) (ref: PRF/09/1)

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	01/07/2014		Yes	No