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Restorelle for laparoscopic sacrocolpopexy for pelvic organ prolapse

Submission date
19/04/2012

Recruitment status
No longer recruiting

Registration date
21/08/2013

Overall study status
Completed

Last Edited
22/02/2019

Condition category
Urological and Genital Diseases

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

Plain English summary of protocol

Background and study aims
Laparoscopic sacrocolpopexy is a prolapse operation which aims to provide support for the vagina and pelvic organs. This is achieved by attaching one end of a piece of special surgical mesh to the top of the vagina and the other end to the lower backbone. Different kinds of mesh can be used for this operation.
The National Institute of Clinical Excellence (NICE) has encouraged healthcare professionals to conduct further research into the different types of mesh currently used for a laparoscopic sacrocolpopexy, as they think that there might be fewer complications with newer types of mesh such as Restorelle, but we need to find out if that is correct.
At the moment there is not enough evidence for us to be able to compare the success rates and complication rates of different types of mesh used for this operation.
The study aims to find out whether using Restorelle mesh for a laparoscopic sacrocolpopexy improves womens prolapse symptoms better than other types of mesh, and whether women who have had this operation using Restorelle mesh have more, the same, or less chance of getting problems following the operation than those who had the same operation but a different type of mesh.

Who can participate?
Women who are eligible to participate in the study are those who have had a laparoscopic sacrocolpopexy performed using Restorelle mesh at Saint Marys Hospital, Manchester. The women must also be willing and able to provide informed consent and complete the study activities.

What does the study involve?
The study involves participants completing a questionnaire to tell us about their prolapse symptoms since the operation and attending an additional follow-up clinic appointment where they will receive a vaginal examination.

What are the potential benefits and risks of participating?
The potential benefit for participants taking part in this research is the satisfaction of helping others by contributing to medical knowledge and an additional follow-up appointment which offers the opportunity to discuss any post-operative issues which may have arisen. We do not

anticipate that any harm will come to you by taking part in the study as it does not involve any treatment or procedure apart from filling in a questionnaire and having a pelvic examination.

Where is the study run from?
The study is being run from The Warrell Unit, Saint Marys Hospital, Central Manchester University Hospital and NHS Foundation Trust.

When is the study starting and how long is it expected to run for?
The study started in May 2012 and ran for 6 months, ending in November 2012.

Who is funding the study?
The study is being funded by Coloplast Corporation, the company who make Restorelle mesh.

Who is the main contact?
Lucy Dwyer (Research Nurse)
The Warrell Unit, Saint Mary's Hospital, UK

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1.1

Study information

Scientific Title
REstorelle for Laparoscopic sacrocolpopexy for pelvic organ prolapse

Acronym
RELease

Study objectives
RELease has been designed to study the performance of Restorelle mesh used for laparoscopic sacrocolpopexy repair of pelvic organ prolapse (POP), to compare the performance of Restorelle mesh with other polypropylene meshes previously used for laparoscopic sacrocolpopexy, to assess quality of life factors, and to assess mesh-related adverse events.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North West - Greater Manchester Central, 17/05/2012, ref: 12/NW/0277

Study design
Retrospective study with prospective follow-up components

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet

Health condition(s) or problem(s) studied
Vaginal prolapse

Interventions
There will be no interventions as a result of study participation.

RELease is an observational follow-up study, therefore participants will be asked to complete a questionnaire and attend an additional follow-up appointment where they will receive a vaginal examination.

Intervention Type
Device

Primary outcome measure

1. To study the performance of Restorelle mesh used for laparoscopic sacrocolpopexy
2. To compare the performance of Restorelle mesh with other polypropylene meshes previously employed for laparoscopic sacrocolpopexy

Secondary outcome measures
1. To assess mesh-related complications, including but not limited to mesh erosion and palpability, based on International Continence Society/International urogynecological association (ICS/IUGA) classification codes
2. To assess the subjective impression of improvement after treatment, via PGI-I (Patient Global Impression of Improvement) Questionnaire for urogenital prolapse
3. To assess condition-specific quality-of-life factors before and after treatment, via the PFDI-20 (Pelvic Floor Distress Inventory-Short Form)

Overall study start date
08/05/2012

Completion date
05/11/2012

Eligibility

Key inclusion criteria
1. Participants must have been previously implanted with Restorelle mesh for laparoscopic sacrocolpopexy treatment of Pelvic Organ Prolapse (POP)
2. Participants must have source data available in physician records and/or database for the retrospective aspect of study
3. Participants must be willing and able to provide informed consent and complete study activities

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
260

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
08/05/2012

Date of final enrolment
05/11/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Warrell Unit
Manchester
United Kingdom
M13 9WL

Sponsor information

Organisation
Manchester Royal Infirmary (UK)

Sponsor details
c/o Lynne Webster
Research & Development
Postgraduate Medical Centre
Oxford Road
Manchester
England
United Kingdom
M13 9WL

Sponsor type
Hospital/treatment centre

Website
http://www.cmft.nhs.uk/

ROR
https://ror.org/03kr30n36

Funder(s)

Funder type
Industry

Funder Name
Coloplast Corporation (Denmark)

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	01/04/2019		Yes	No