

Restorelle for laparoscopic sacrocolpopexy for pelvic organ prolapse

Submission date 19/04/2012	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 21/08/2013	Overall study status Completed	☐ Statistical analysis plan
		☒ Results
Last Edited 22/02/2019	Condition category Urological and Genital Diseases	☐ 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

Ms Lucy Dwyer

Contact details

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Additional identifiers

Protocol serial number

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

Primary study design

Observational

Study design

Retrospective study with prospective follow-up components

Study type(s)

Screening

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(s)

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

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

United Kingdom

England

Study participating centre

The Warrell Unit

Manchester

United Kingdom

M13 9WL

Sponsor information

Organisation

Manchester Royal Infirmary (UK)

ROR

<https://ror.org/03kr30n36>

Funder(s)**Funder type**

Industry

Funder Name

Coloplast Corporation (Denmark)

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	01/04/2019		Yes	No