Feasibility of biologic OviTex mesh in ventral mesh rectopexy: a pilot study

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- To examine the safety and feasibility (i.e. technical end result) of using OviTex core PGA during VMR - To assess perioperative complications- To assess 90-day morbidity

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON49296

Source
ToetsingOnline

Brief title
Pilot VMR OviTex

Condition

- Gastrointestinal therapeutic procedures

Synonym
intussusception, Rectal prolapse

Research involving
Human

Sponsors and support

Primary sponsor: Meander Medisch Centrum
Source(s) of monetary or material Support: GDM,GDMedical levert kosteloos 15 OviTex matten

Intervention

Keyword: Biologic mesh, OviTex, Rectal prolapse, Ventral rectopexy

Outcome measures

Primary outcome

To examine the safety and feasibility of using OviTex core PGA during VMR.

Secondary outcome

Not applicable

Study description

Background summary

Minimal-invasive ventral mesh rectopexy (VMR) is a widely accepted treatment for patients suffering from rectal prolapse. Choice of material used in VMR remains subject of debate. Currently, the most widely used mesh in VMR is polypropylene and has shown good results regarding recurrence, mesh exposure and functional outcome. Although complication rates are low, the risk of fistulation, erosion and dyspareunia are serious complications and form a reason to opt for biological mesh. High-quality literature of synthetic versus biological mesh is lacking, but does not stop resistance against synthetic mesh from growing. The available literature does not suggest a better nor worse performance of biologic mesh (Biodesign or Permacol) over synthetic polypropylene mesh regarding risk on recurrence and functional outcome. There might be a lower risk on mesh related complications.
OviTex is a biologic mesh that is designed to reinforce weakened tissue. It is fabricated from sterile ovine (sheep) extracellular matrix. The material is similar to Biodesign mesh but is available at a lower cost. OviTex would be a good alternative for polypropylene in VMR. In the search for the most optimal surgical mesh for VMR, OviTex should therefore be investigated. Although it has been used for some patients in VMR, there is no literature on OviTex in VMR to date. A pilot study should be conducted first to test the feasibility and safety in this surgery.

Study objective

- To examine the safety and feasibility (i.e. technical end result) of using OviTex core PGA during VMR
- To assess perioperative complications

- To assess 90-day morbidity

Study design

Prospective double-centre observational pilot study with 15 patients

Intervention

Minimal-invasive ventral mesh rectopexy with an OviTex mesh

Study burden and risks

Although OviTex has not been used on a large scale for VMR before, the strength of OviTex meets that of the current standardly used synthetic meshes. Patients that participate could possibly benefit from the lower synthetic load inserted in their bodies which might bring a lower risk on mesh related complications. Based on current literature on biologic mesh it cannot be expected that these patients will have a higher nor lower risk on recurrence compared to synthetic mesh. We have been noticing an aversion to synthetic mesh in a proportion of our patients. With OviTex, those patients can be helped now too, which could benefit their health and quality of life.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Indication for ventral mesh rectopexy
Informed consent for OviTex mesh
Age of 18 years or older

Exclusion criteria

Mental incompetence
Allergy to ovine rumen.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-01-2021
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	OviTex reinforced bioscaffold
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	16-10-2020
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL74593.100.20