

# Laparoscopic sacrocolpopexy versus open abdominal sacrocolpopexy for vaginal vault prolapse: A long term follow-up on quality of life and anatomical result

No registrations found.

<b>Ethical review</b>	Not applicable
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON22345

### Source

Nationaal Trial Register

### Brief title

SALTO: Long term follow-up

### Health condition

sacrocolpopexy  
sacral colpopexy  
pelvic organ prolapse  
vault prolapse  
sacrocolpopexie  
prolaps  
vaginatopprolaps  
verzakking

## Sponsors and support

**Primary sponsor:** Máxima Medical Centre, Veldhoven

**Source(s) of monetary or material Support:** Máxima Medical Centre, Veldhoven. Prof.dr.

## Intervention

## Outcome measures

### Primary outcome

The primary objective of this follow-up study is to evaluate long term outcome in terms of disease specific quality of life of the patient population of the SALTO1 trial.

### Secondary outcome

The secondary objective of this follow-up study is to evaluate long term outcome in terms of patient's subjective satisfaction, general quality of life, sexual functioning, subjective and objective recurrence, type and number of re-interventions and mesh and suture erosion in the patient population of the SALTO1 trial.

## Study description

### Background summary

SALTO: long term follow-up is a follow-up trial of the SALTO study. Primary outcome is disease specific quality of life. Secondary outcome is patient's subjective satisfaction, general quality of life, sexual functioning, subjective and objective recurrence, type and number of re-interventions and mesh and suture erosion.

### Study objective

Based on our primary results we do not expect anatomical difference between the two groups. However, we expect to see more erosion as compared to 1 year of follow-up.

### Study design

3-10 years postoperative:

- Questionnaire
- Physical examination using POP-Q classification

### Intervention

Since this is a follow-up study, no interventions will be done.

Patientes are asked to fill out a questionnaire and to come to the outpatient clinic once for a physical examination using POP-Q classification.

## Contacts

### **Public**

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## Eligibility criteria

### **Inclusion criteria**

- All patients from the original SALTO trial.
- Willing to participate

### **Exclusion criteria**

- Died patients
- Unwilling to participate.
- Unable to visit the outpatient clinic.

## Study design

### Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-03-2017
Enrollment:	74
Type:	Anticipated

## Ethics review

Not applicable	
Application type:	Not applicable

## 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
NTR-new	NL5964
NTR-old	NTR6330
Other	60618 : ABR

## Study results

### Summary results

Coolen A-LWM, van Oudheusden AMJ, Bongers MY, et al. A Comparison of Complications between Open Abdominal Sacrocolpopexy and Laparoscopic Sacrocolpopexy for the Treatment of Vault Prolapse. *Obstetrics and Gynecology International*. 2013;2013:528636. doi:10.1155/2013/528636.