

# Laparoscopic sterilization and diagnostic laparoscopy under general anesthesia or conscious sedation; a randomized controlled trial

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Main objective is to determine whether patients have a better recovery after laparoscopic sterilization or a diagnostic laparoscopy under conscious sedation compared to general anesthesia as measured with the QoR-40 one day after surgery.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Reproductive tract disorders NEC
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON56040

### Source

ToetsingOnline

### Brief title

Laparoscopic procedures under general anesthesia or conscious sedation

### Condition

- Reproductive tract disorders NEC

### Synonym

diagnostic laparoscopy, Female sterilization

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Catharina-ziekenhuis

**Source(s) of monetary or material Support:** Er is geen separate geldstroom voor dit onderzoek; de sedatie of algehele anesthesie valt onder de standaard zorg

## Intervention

**Keyword:** Conscious sedation, General anesthesia, Patients' recovery, Sterilisation

## Outcome measures

### Primary outcome

Main outcome measure is total patients\* recovery as measured with the Quality of Recovery 40 questionnaire (QoR-40) one day after surgery.

### Secondary outcome

Secondary outcome measures are the number of complications, operating times, recovery times, peri-operative parameters such as heart rate, blood pressure and saturation, and late patients\* recovery as measured with the Recovery Index-10 (RI-10).

## Study description

### Background summary

Laparoscopic sterilization or a diagnostic laparoscopy are common minimally invasive procedures. A recently published systematic review shows that patients\* might benefit from a laparoscopic procedure using conscious sedation compared to general anesthesia. However, only few and relatively old studies could be included, pointing out the importance of new research regarding this subject.

### Study objective

Main objective is to determine whether patients have a better recovery after laparoscopic sterilization or a diagnostic laparoscopy under conscious sedation compared to general anesthesia as measured with the QoR-40 one day after surgery.

### Study design

## Intervention

The control group will undergo sterilization or a diagnostic laparoscopy under general anesthesia; the intervention group will receive conscious sedation using Propofol and Fentanyl.

## Study burden and risks

In this study with capacitated adults no additional risks are expected compared to patients who undergo a laparoscopic sterilisation or a diagnostic laparoscopy without participating in the study. Patients\* burden of completing questionnaires about their health and recovery both before and after surgery is in proportion to the potential value of our research.

## Contacts

### Public

Catharina-ziekenhuis

Michaelangelolaan 2  
Eindhoven 5623 EJ  
NL

### Scientific

Catharina-ziekenhuis

Michaelangelolaan 2  
Eindhoven 5623 EJ  
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

## Inclusion criteria

Wish for female sterilization with Filshie clips or indication for diagnostic laparoscopy

## Exclusion criteria

- Being younger than 18 years old
- Not understanding the Dutch language
- ASA classification 3 or 4 and therefore not being eligible for conscious sedation in our clinic
- Extensive abdominal surgery in the past which high chance of adhesions

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	16-06-2021
Enrollment:	76
Type:	Actual

## Ethics review

Approved WMO

Date:	25-10-2019
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	
Date:	08-03-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	
Date:	04-10-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	
Date:	18-11-2024
Application type:	Amendment
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	NL68039.100.18
Other	NTR-7092