Conscious Sedation or General Anesthesia for Laparoscopic Sterilisation

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20118

Source
Nationaal Trial Register

Health condition

laparoscopy, sterilization, sedation, general anesthesia.
Laparoscopie, sterilisatie, sedatie, algehele anesthesie

Sponsors and support

Primary sponsor: Catharina Hospital, Eindhoven
Source(s) of monetary or material Support: Same as sponsor

Intervention

Outcome measures

Primary outcome

Total patients’ recovery as measured with the Quality of Recovery 40 questionnaire (QoR-40) one day after surgery

Secondary outcome

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

Female sterilization is the most popular and common contraceptive method worldwide.A recently published systematic review shows that patients might benefit from a laparoscopic sterilization
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.Therefore, we will perform a randomized controlled trial to study the difference in patients' recovery when using conscious sedation instead of general anesthesia for laparoscopic sterilization.

Study objective

Patients have a better recovery after laparoscopic sterilization under conscious sedation compared to general anesthesia as measured with the QoR-40 one day after surgery.

Study design

1. Admission, surgery and recovery time and peri-operative parameters during admission

2. Patients' recovery 1 day after surgery

3. Patients' recovery 1 week after surgery

4. Complications until 6 weeks after surgery

Intervention

Conscious sedation versus general anesthesia

Contacts

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Eligibility criteria

Inclusion criteria

- 18 years or older

- Classificantion: ASA 1 or 2

- Being able to understand the Dutch language

Exclusion criteria

- Younger than 18 years

- no Dutch speaking

- Extensive abdominal surgery in the past which high chance of adhesions

- Classification ASA 3 of 4

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-10-2019
Enrollment:	46
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Ethics review

Positive opinion

Date:	27-02-2018
Application type:	First submission

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	NL5526
NTR-old	NTR7092
Other	MEC-U : R19.006

Study results