Evaluation of the clinical- & cost-effectiveness of UltraSOund-guided RadioFrequency Ablation of Leiomyomas via the Transvaginal route (ESONATA)

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24224

Source
NTR

Brief title
ESONATA

Health condition

intrauterine leiomyomas, intrauterine fibroids, heavy menstrual bleeding

Sponsors and support

Primary sponsor: Máxima Medical Center
Source(s) of monetary or material Support: Máxima MC

Intervention

Outcome measures

Primary outcome

Time to return to work in days

Secondary outcome

Uterine fibroid symptom and health-related quality of life, Reintervention rate, Complications,Costs, Satisfaction and recommendation to friend

Study description

Background summary

Uterine leiomyomas are the most common neoplasms affecting adult women with a prevalence rate of ~20-25% which often require intervention. Hysterectomy and tomic myomectomy are common treatment in the Netherlands which are associated with morbidity and productivity loss. An alternative less invasive therapy is intrauterine ultrasound (IUUS)-guided transvaginal radiofrequency (RF) ablation. Although good results are accomplished for this therapy in single-arm trials, comparative and cost-effectiveness studies needed for broad implementation are lacking. Therefore, the present study is being undertaken to compare disease-specific quality of life and the cost-effectiveness of IUUS-RF ablation of leiomyomas with the Sonata system compared to usual care (total laparoscopic hysterectomy, and tomic myomectomy) in a prospective, single center, cohort study.

Study objective

The removal of intrauterine leiomyomas through transvaginal ultrasound-guided radiofrequency ablation is a clinical- and cost-effective alternative for laparoscopic hysterectomy and tomic myomectomy.

Study design

Baseline, 6, 12 and 18 months after intervention

Intervention

Removal of intrauterine leiomyomas through transvaginal ultrasound-guided radiofrequency ablation (Sonata system)

Contacts

Public
Máxima Medisch Centrum
Marlies Bongers

040-8888384
Scientific
Máxima Medisch Centrum
Marlies Bongers

040-8888384

Eligibility criteria

Inclusion criteria

1. Have selected Sonata, tomic myomectomy, laparoscopic hysterectomy for the treatment of leiomyomas
2. Presence of at least one submucous myoma (type 2) or transmural fibroid (type 2-5)
3. ≥ 25 years of age at the time of enrollment
4. American Society of Anesthesiologist class 1 or 2

Exclusion criteria

1. Clotting disorders
2. Inability to understand Dutch or English

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-12-2019

Enrollment:	99
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

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	NL8248
Other	Commissie Lokale Uitvoerbaarheid Máxima Medical Center : L19.135

Study results