TCRM study

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26316

Source
NTR

Brief title
TCRM study

Health condition

TCRM
Transcervical
Resection
Myoom
Myoma
Fibroid

Sponsors and support

Primary sponsor: VUMC
Source(s) of monetary or material Support: fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

Reduction of menstrual blood loss (measured with Pictorial Blood Assessment Chart (PBAC)).

Secondary outcome

Reduction of menstrual pain (use of painkillers will be registered)
Reduction of symptoms and improvement of health related quality of life (measured with UFS QOL NL)
Increase in serum Hb value
Surgical outcome parameters, including surgery time, fluidloss, blood loss, percentage of resection, complications, recovery

Study description

Background summary

Patients are asked to fill in 3 questionnaires and keep a period diary.

Study objective

Submucous fibroids are known to be related to heavy menstrual bleeding (HMB), dysmenorrhea and fertility problems. Transcervical resection of fibroids (TCRM) is a widely implemented treatment for submucous fibroids, to be precise FIGO PALM-COEIN classification type 0, 1 and 2 fibroids. However, reduction of abnormal uterine bleeding after TCRM has never been quantified. Aim: to demonstrate reduction of heavy menstrual bleeding after TCRM (PBAC score).

Study design

Not applicable

Intervention

Trans Cervical Resection of Myoma

Contacts

Public
VUMC
PK 6Z-162
De Boelelaan 1118
A.L. Keizer
Amsterdam 1081 HZ
The Netherlands

Scientific
VUMC
PK 6Z-162
De Boelelaan 1118
A.L. Keizer
Amsterdam 1081 HZ
The Netherlands

Eligibility criteria

Inclusion criteria

FIGO (PALM-COEIN) classification submucous uterine fibroids type 0, 1 and 2
Women with heavy menstrual bleeding defined as PBAC score > 150 (= 120 ml)
Maximum of 2 submucous fibroids
Maximum fibroid diameter of 4 cm
Residual myometrium between fibroid capsule and serosa of at least 5 mm
Regular cycle (with or without oral contraceptives)

Exclusion criteria

Age below 18 years
Women who do not master the Dutch or the English language
Pregnancy
Congenital uterine abnormalities, except for arcuate uterus
Presence of FIGO (PALM-COEIN) classification type 3-4 and type 2-5 fibroids
Use of GnRH analogs or Ulipristal
Known coagulopathy or use of heparine or coumarine derivates
Other disorders that may induce HMB (polyps, known atypical endometrial cells, cervical dysplasia, cervical or pelvic infection, assumed malignancy, irregular cycle >35 days or intercycle variation of 2 weeks or more)
Contra-indications for general or spinal anaesthesia or conscious sedation
Women not willing to participate

Study design

Design

Study type: Observational non invasive

Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2014
Enrollment:	150
Type:	Anticipated

Ethics review

Positive opinion

Date:	21-01-2014
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	NL4270
NTR-old	NTR4406
Other	METC VUMC : 2013.379

Study results