MYOMEX-2

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Ulipristal acetate (UPA) is non-inferior to surgical treatment measured by UFS-QOL (Symptom Severity) scores.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25181

Bron
Nationaal Trial Register

Verkorte titel
MYOMEX-2

Aandoening

symptomatic uterine fibroids

Symptomatische uterine myomen

Ondersteuning

Primaire sponsor: Vrije Universiteit Medisch Centrum
Overige ondersteuning: ZonMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary outcomes with regard to patient:
1) Fibroid-specific quality-of-life, measured by the Uterine Fibroid Symptom-questionnaire (UFS-QOL) symptom severity score (SSS)outcome at 24 months after randomization.

Primary outcomes with regard to costs (using internet medical consumption questionnaires; iMCQ):
1) Direct healthcare costs
2) Costs due to loss of productivity (absenteeism from work)
3) Patient costs (informal care, other care services paid for by patients themselves)

Toelichting onderzoek

Achtergrond van het onderzoek

Uterine fibroids are very common during reproductive years in women. Ulipristal acetate (UPA), a selective progesterone receptor modulator, was introduced in 2012 as a new treatment option for symptomatic uterine fibroids. UPA induces a volume reduction and Uterine Fibroid Symptoms questionnaires filled in by the patients revealed a improvement in quality-of- life and reduction in symptom scores. UPA was launched as a revolutionary medication for fibroids, claiming to make invasive treatment unnecessary. However, UPA is quite costly and has never been compared to other treatment modalities. In this study we will compare UPA with standard surgical treatment (hysterectomy, myomectomy or uterine artery embolization), to study the effect in quality of life, symptom severity scores and health-care costs (primary outcomes) between both treatments. This is a multicenter trial which will be performed in the Netherlands.

Doel van het onderzoek

Ulipristal acetate (UPA) is non-inferior to surgical treatment measured by UFS-QOL (Symptom Severity) scores.

Onderzoeksopzet

Baseline, with

24 months of follow-up

Onderzoeksproduct en/of interventie

Patients are randomly assigned in a 2:1 ratio to two groups. One group (N=60) will receive no

additional medicinal treatment and will undergo standard surgical treatment (hysterectomy, myomectomy or uterine artery embolization). The other group (N=119) will receive the medicinal treatment (daily one 5 mg tablet of UPA during 12 weeks), followed by a drug-free interval of 2 months. In total, the treatment course will be administered three times, or – when desired and well tolerated- a maximum of four times. In total patients will be ‘on treatment’ for 13-18 months (depending on the amount of treatment courses).

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Women visiting the gynecological outpatient clinic with symptomatic fibroids will be screened for eligibility. In order to be eligible to participate in this trial, a subject must meet all of the following criteria:

- Symptomatic fibroids warranting surgical treatment, either hysterectomy, myomectomy or uterine artery embolization

- Conservative treatment failed or is undesired

- Pre-menopausal

- >18 years of age

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- Asymptomatic fibroids

- Current pregnancy or unwillingness to use contraception

- Suspicion of malignancy

- Current use of Ulipristal

- Contra-indication for the use of Ulipristal

- Not willing or able to give written informed consent

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-11-2018
Aantal proefpersonen:	179
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	04-12-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6690
NTR-old	NTR6860
Ander register	NL62638.029.17 : ABR-kenmerk

Resultaten