Reproductive outcomes in women with fibroids or after removal of fibroids: a retrospective cohort study.

Gepubliceerd: 16-08-2019 Laatst bijgewerkt: 13-12-2022

Surgical treatment of myomas can have a positive effect on the tome until ongoing pregnancy and decrease the risk of premature birth and miscarriages, but is depended on number, localization, size, and type of myoma.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21452

Bron
NTR

Verkorte titel
MyoFert

Aandoening

myomas (fibroids)

Ondersteuning

Primaire sponsor: VU medical centre
Overige ondersteuning: N/A

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Time until live birth

Toelichting onderzoek

Achtergrond van het onderzoek

Patients with asymptomatic myomas have a reduced risk of spontaneous pregnancy and an increased risk of premature birth and miscarriages. However, the extent of this effect is still insufficiently known, because the literature often does not include the type, number and localization of the myoma(s). Surgical treatment of myomas are frequently performed to treat gynecological complaints and/or improve pregnancy outcomes. The long-term outcomes of these interventions have not been sufficiently investigated with regard to the reproductive outcomes. These results are important for counseling patients considering such an intervention, but also for setting up a future (randomized) study.
The primary objective is to study pregnancy outcomes in patients with asymptomatic myomas without further interventions related to spontaneous pregnancy and an increased risk of premature birth and miscarriages. We want to see if number, localization, size, and type of myoma influences these outcomes. We want to investigate the same in women who have had a myoma treatment. We want to look both at women who have had surgical treatment on the myomas to promote fertility outcomes and also at women who received this from gynecological complaints.

Doel van het onderzoek

Surgical treatment of myomas can have a positive effect on the tome until ongoing pregnancy and decrease the risk of premature birth and miscarriages, but is depended on number, localization, size, and type of myoma.

Onderzoeksopzet

One survey with questions about complaints, pregnancy and treatment of myomas.

Contactpersonen

Publiek

VUmc
Emmy Don

020-444 4809

Wetenschappelijk

VUmc
Emmy Don

020-444 4809

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients that visited the VUmc, Amsterdam UMC, with myomas between 2004-2018.
Age at visitation between 18 and 45.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients that visited the VUmc, Amsterdam UMC, with myomas before 2004 or after 2018.
Age at visitation between <18 or >45
Patients with intrauterine abnormalities of the uterine cavity other than myomas or endometrial polyps. Such as congenital uterine abnormalities, uterine septum, dominant adenomyosis, malignancies, dominant intrauterine adhesions/Asherman syndrome.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	16-08-2019
Aantal proefpersonen:	500
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting
N/A

Ethische beoordeling

Positief advies

Datum:	16-08-2019
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	NL7990
Ander register	MEC Amsterdam : protocol number 2019.225

Resultaten

Samenvatting resultaten
N/A