

The use of CEUS in the assessment of uterine fibroids, a feasibility study.

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We think that CEUS has an additional value in identifying the (micro)vasculature of uterine fibroids compared to 3D power Doppler ultrasound. We hypothesize that in the future CEUS could be useful for the prediction of fibroid responsiveness for...

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

Samenvatting

ID

NL-OMON26440

Bron

NTR

Aandoening

fibroids, contrast enhanced sonography, ultrasound

Ondersteuning

Primaire sponsor: VU medical center

Overige ondersteuning: none

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- To test the feasibility of CEUS in visualizing uterine leiomyomas and their vascularization.
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- To observe the enhancement pattern and time-intensity curve obtained from CEUS.

Toelichting onderzoek

Achtergrond van het onderzoek

With Contrast Enhanced UltraSound (CEUS) the microvascularisation of uterine leiomyomas can be visualized with the potential to improve ultrasound imaging for uterine leiomyoma detection. This can be useful for treatment choice and therapeutic monitoring of uterine leiomyomas. The past years numerous studies have been performed with CEUS, but only a few small series were reported on using CEUS in the assessment of uterine leiomyomas. To our knowledge there are no studies that compare the diagnostic value of CEUS in identifying uterine leiomyomas compared to 3D power Doppler, with MRI as a reference standard, which is the aim of this current study.

Multicenter: VUmc and AMC

Doel van het onderzoek

We think that CEUS has an additional value in identifying the (micro)vasculature of uterine fibroids compared to 3D power Doppler ultrasound. We hypothesize that in the future CEUS could be useful for the prediction of fibroid responsiveness for specific therapies and for the monitoring of uterine leiomyomas. We will use dynamicMRI as a reference standard.

Onderzoeksopzet

Patients will receive one dynamic MRI and at one timepoint a contrast sonography of the uterus.

Onderzoeksproduct en/of interventie

Patients will undergo a 3D power Doppler, CEUS and a MRI-scan.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Older than 18 years of age; Suspected uterine leiomyomas; scheduled for dynamic MRI

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Postmenopausal woman
- Women with an known allergy to SonoVue or any of its components
- Woman with an history of any clinically unstable cardiac condition including class III/IV cardiac failure or right to left shunts
- Woman who have had a severe cardiac rhythm disorders within the last 7 days
- Woman with severe pulmonary hypertension or systemic hypertension treated or not treated or women with respiratory distress syndrome
- Contra-indications for dynamic MRI
- Pregnant and lactating women.

Onderzoeksopzet

Opzet

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

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-06-2014
Aantal proefpersonen:	10
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	16-01-2014
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	NL4266

Register

NTR-old

Ander register

ID

NTR4402

METC : 2014_087

Resultaten

Samenvatting resultaten

N/A