Recognizing patients with (a higher risk of) endometrial cancer; the role of fat distribution and inflammation in the origin of endometrial cancer, a study that focuses on prevention and prediction

Gepubliceerd: 23-07-2021 Laatst bijgewerkt: 18-08-2022

We hypothesize that BMI, the type of fat distribution, and possibly the underlying illness significantly influence the change in hormone levels, and systemic inflammation levels after bilateral salpingo-oophorectomy (BSO). In EC patients , systemic...

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

Samenvatting

ID

NL-OMON28456

Bron
NTR

Verkorte titel
ENDOCRINE

Aandoening

Endometrial cancer

Ondersteuning

Primaire sponsor: AAF (Academic Alliance Foundation)
Overige ondersteuning: Academic Alliance Foundation

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To compare hormone levels and inflammatory markers before and after BSO in obese and non-obese subjects.

Toelichting onderzoek

Achtergrond van het onderzoek

The impact of BMI and fat distribution (subcutaneous vs. visceral) on hormone levels and inflammation is not clear. Yet, understanding these interactions in general is highly relevant, and in particular for better understanding and treatment of endometrial cancer (EC) in increasingly obese patients. Standard surgical treatment of EC and of adnexal masses gives access to both the subcutaneous and the visceral adipose tissue, and facilitates to study these important relations. We hypothesize that BMI, the type of fat distribution, and possibly the underlying illness significantly influence the change in hormone levels, and systemic inflammation levels after bilateral salpingo-oophorectomy (BSO). In EC patients , systemic inflammation markers are expected to be higher compared to controls. Also, we expect the ratio of visceral:subcutaneous fat to be higher in these women, as visceral fat tissue is considered to be more metabolic active. Finally, we expect that BSO in obese women result in only slight decrease in estrogen levels.

Doel van het onderzoek

We hypothesize that BMI, the type of fat distribution, and possibly the underlying illness significantly influence the change in hormone levels, and systemic inflammation levels after bilateral salpingo-oophorectomy (BSO). In EC patients , systemic inflammation markers are expected to be higher compared to controls. Also, we expect the ratio of visceral:subcutaneous fat to be higher in these women, as visceral fat tissue is considered to be more metabolic active. Finally, we expect that BSO in obese women result in only slight decrease in estrogen levels.

Onderzoeksopzet

Pre-operation, during operation, 6 weeks after operation

Onderzoeksproduct en/of interventie

Preoperatively: All included subjects are requested to consent for blood sample analysis,

undergoing CT-scan and fill in three questionnaires. During surgery, fat tissue and (in cases) tumour tissue will be collected. Six weeks after surgery blood will be obtained from all subjects once more and one questionnaire repeated.

Contactpersonen

Publiek

MUMC
Anouk van den Bosch

0630575778

Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- CASES (n=80): - pre- and perimenopausal BMI ≥35 (n=20)
- pre- and perimenopausal BMI 18-25 (n=20)
- postmenopausal BMI ≥35 (n=20)
- postmenopausal BMI 18-25(n=20)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Other malignancy <5 years prior to inclusion, except basal cell carcinoma
- Use of systemic hormonal therapy <3 months
- Insufficient understanding of the Dutch language
- Subjects not allowed to undergo CT-scan
- Women (cases as well as controls) with BMI between 25.1-34.9

- Women who are expected to be offered HRT after surgery

CONTROLS (n=80): - Pre- and perimenopausal BMI ≥35 (n=20)
- Age >40 years
- pre- and perimenopausal BMI <25 (n=20)
- postmenopausal BMI ≥35 (n=20)
- postmenopausal BMI 18-25(n=20)

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-08-2021
Aantal proefpersonen:	160
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	23-07-2021
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	NL9622
Ander register	METC AZM/UM : METC 21-011

Resultaten