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

No registrations found.

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

Summary

ID

NL-OMON28456

Source
NTR

Brief title
ENDOCRINE

Health condition

Endometrial cancer

Sponsors and support

Primary sponsor: AAF (Academic Alliance Foundation)
Source(s) of monetary or material Support: Academic Alliance Foundation

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

To compare the effect of fat distribution and etiology on changes in hormone levels and inflammatory markers due to BSO in obese and non-obese subjects as well as the effect of BSO on menopausal complaints.

Study description

Background summary

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.

Study objective

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.

Study design

Pre-operation, during operation, 6 weeks after operation

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

- 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)

Exclusion criteria

- 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)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2021
Enrollment:	160
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	23-07-2021
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	NL9622
Other	METC AZM/UM : METC 21-011

Study results