HIRISE (High-Risk women and hormonal Substitution Exposure).

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20562

Source
Nationaal Trial Register

Brief title
HIRISE

Health condition

Women with an increased risk for breast- and ovarian cancer due to a genetic prediposition, after prophylactic adnectomy.

Sponsors and support

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Intervention

Outcome measures

Primary outcome

1. Change in mammographic breast density;

2. Menopausal symptoms and sexuality.

Secondary outcome

1. Generic quality of life;

2. Compliance;

3. Bone density;

4. Incidence of benign breast disorders;

5. Incidence of breast carcinoma (in situ and invasive);

6. Incidence of other malignancies;

7. Incidence of gynecological disorders;

8. Incidence of cardiovascular disease;

9. Incidence of biliary surgery;

10. Incidence of bone fractures;

11. LDL and HDL levels;

12. Androgen levels.

Study description

Background summary

N/A

Study objective

The aim of the study is:

1. To investigate the benefits and risks of hormonal substitution after prophylactic adnectomy in women with an increased risk for breast- and/or ovarian cancer due to a genetic predisposition;

2. To compare the effects and side-effects of conjugated estrogens, continuously combined with medroxyprogesterone acetate and tibolone.

Study design

N/A

Intervention

Patients will be randomized to receive either:

1. 0.625 mg conjugated estrogens and 5 mg medroxyprogesterone acetate continuously combined (arm1) or

2. 2.5 mg tibolone continuously (arm 2).

Treatment will be preferentially administered for a period of at least two years. However, patients up to 50 years of age are eligible for the study as long as they intend to take the treatment medication for at least two years. In all patients, treatment may be continued until the age of 52 years, regardless the age at study entry.

Registration study:

Eligible women who are not willing to participate in the study because the absence of menopausal complaints and/or reluctance to take hormones will be asked to participate in a concomitant registration study.

In this group of women, the endpoints that will be measured and the data to collect are identical to the endpoints and data for the women participating in the intervention study.

Contacts

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Eligibility criteria

Inclusion criteria

1. Prophylactic adnectomy not longer than five years ago, or scheduled to undergo prophylactic adnectomy within the next six months from randomization;

2. Age 25-50 years;

3. Premenopausal at the time of prophylactic adnectomy;

4. Either proven BRCA 1 or BRCA 2 mutation carrier or member of an HBOC-family (50% risk carrier);

5. Have intact breast tissue (and do not consider prophylactic mastectomy in the next year);

6. Informed consent has been obtained.

Exclusion criteria

1. HST/ OAC (oral anticonceptive) intake in the last three months;

2. History of breast cancer. Patients who have had adequately treated skin cancer (non-melanoma) or cervical carcinoma in situ are eligible. Furthermore, patients who have had another malignancy in the past, but have been disease free for more than 5 years are also eligible;

3. Abnormality on mammography that, according to the attending physician or radiologist, requires further diagnostic or therapeutic intervention;

4. Concomitant cardiovascular illness including: (recent) myocardial infarction, uncontrolled cardiac arrhytmias, angina pectoris, uncontrolled hypertension, and heart failure;

5. Current or history of deep venous thrombosis, thrombophlebitis, thromboembolic disease or suspicion of hereditary predisposition for developing venous thromboembolic disease or use of anticoagulation;

6. Abnormal endometrial thickness. For women having the ovaries still in situ, there is no maximum thickness. However, in women who were not exposed to endogenous or exogenous estrogens over the last three months, the double layer endometrial thickness should be less than 4 mm;

7. Hysterectomy;

8. Abnormal Pap smear;

9. Known or suspected hypersensitivity to estrogen and/or progesterone and/or tibolone;

10. Concomitant disease for which the use of exogenous hormonal steroids is contraindicated;

11. Use of one or more of the following drugs within the last two months: hepatic microsomal enzyme-inducing anticonvulsant drugs or drugs known to affect or interfere with the pharmacokinetics of steroids (e.g. hydantoins and/or barbiturates, such as phenobarbital, Bellergal®, rifampicin, griseofulvin, primidone or carbamazepine);

12. Use of investigational drugs within the past 6 months;

13. Alcohol and/or drug abuse within the last 3 months or any other condition that might result in premature discontinuation, according to the opinion of the investigator;

14. Abnormal laboratory values considered being clinically relevant by the investigator.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-09-2004
Enrollment:	177
Type:	Anticipated

Ethics review

Positive opinion

Date:	22-03-2006
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	NL581

Register	ID
NTR-old	NTR637
Other	: N/A
ISRCTN	Incomplete info for ISRCTN

Study results

Summary results
N/A