

The effect of hormonal replacement therapy on menopausal complaints related to biochemical changes in surgically and naturally postmenopausal women.

A prospective observational comparative study.

Published: 19-09-2006

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The aims of this prospective study are to investigate:1a: Changes in menopausal symptoms and biochemical changes as result of PBSO in premenopausal women.1b: Changes in menopausal symptoms and biochemical changes as result of PBSO in postmenopausal...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Reproductive tract and breast disorders congenital
Study type	Observational invasive

Summary

ID

NL-OMON30054

Source

ToetsingOnline

Brief title

HRT at surgical menopause

Condition

- Reproductive tract and breast disorders congenital
- Menopause related conditions

Synonym

1 - The effect of hormonal replacement therapy on menopausal complaints related to b ... 24-05-2025

menopause

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis

Source(s) of monetary or material Support: sponsorgelden

Intervention

Keyword: Hormone Replacement Therapy, Hormones, Menopause, Questionnaires

Outcome measures

Primary outcome

Endocrine symptoms score

Hot flush score

Estrogens, Testosterone, DHEAS, Serotonine, 5-HT_{2A}-receptor

Secondary outcome

Sexual functioning score

Depression and anxiety score

Progesterone, LH, FSH, Cortisol, SHBG, Prolactin, Oxytocin, Catecholamines and

β-Endorphin

Study description

Background summary

A recent study found that the effectiveness of Hormonal Replacement Therapy (HRT) for alleviating endocrine and/or sexual complaints and quality of life was of limited importance for surgically postmenopausal women. An explanation for this effect may be found in the hypothalamic-pituitary-adrenal axis (HPA axis) and the hypothalamic-pituitary-gonadal axis (HPG axis). The possible differences on the various hormone concentrations of sex hormones or neurotransmitters between surgically and naturally postmenopausal women could

be an explanation for the results of HRT by these women.

Study objective

The aims of this prospective study are to investigate:

1a: Changes in menopausal symptoms and biochemical changes as result of PBSO in premenopausal women.

1b: Changes in menopausal symptoms and biochemical changes as result of PBSO in postmenopausal women.

2: Difference in intensity of menopausal symptoms and related biochemical parameters between surgically and naturally postmenopausal women (control group 2).

3: The effect of HRT in alleviating menopausal complaints and related biochemical parameters in surgically postmenopausal women compared to naturally postmenopausal women (control group 1).

4: Difference in menopausal symptoms and related biochemical parameters in surgically postmenopausal women between HRT and non-HRT users.

5: The prevalence of serotonin receptor (5-HT_{2A} receptor) and serotonin polymorphism (5-HTTLPR) in surgically postmenopausal women with respect to the effect of HRT use.

Study design

Prospective observational and longitudinal study

Study burden and risks

Group1: 4 times blood donations and 3 questionnaires

Group2: 2 times blood donations and 2 questionnaires

Group3: Once blood donation and 1 questionnaire

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

gr 1) Eligible to undergo PBSO

Either proven BRCA 1 or BRCA 2 mutation carrier or member of an HBOC-family

gr 2) Last menses >3 months ago

Menopausal complaints

gr 3) Age ≥ 46 and < 56 years

Last menses >3 months, <3 years

Exclusion criteria

gr 2 : Hormone use (contraceptives or HRT)

Study design

Design

Study type: Observational invasive

Intervention model: Other

Allocation: Non-randomized controlled trial

Masking: Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 25-09-2006

Enrollment: 280

Type: Actual

Ethics review

Approved WMO

Date: 19-09-2006

Application type: First submission

Review commission: PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

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

CCMO

ID

NL11371.031.06