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
Last updated: 10-08-2024

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

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-HT2A-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-HT2A 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

Public
Antoni van Leeuwenhoek Ziekenhuis

Plesmanlaan 121
1066CX
Nederland
Scientific
Antoni van Leeuwenhoek Ziekenhuis

Plesmanlaan 121
1066CX

Nederland

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	ID
CCMO	NL11371.031.06