The role of diurnal cortisol rhythm in relation to personality and QoL with regard to morbidity, prognosis and mortality in patients with suspicion of breast cancer

Published: 20-02-2007
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The aim of the study will be to examine the relationship between personality, QoL and diurnal cortisol rhythm in women with a suspicion of breast cancer with regard to morbidity, prognosis and mortality.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Breast neoplasms malignant and unspecified (incl nipple)
Study type	Observational non invasive

Summary

ID

NL-OMON31596

Source
ToetsingOnline

Brief title
N.A.

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
Breast Cancer, Breast Neoplasm

Research involving
Human

Sponsors and support

Primary sponsor: Sint Elisabeth Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cortisol rhythm, personality, prognosis, quality of life

Outcome measures

Primary outcome

Primary study parameters: personality, Quality of life, cortisol rhythm

Outcome of the study: recurrence, morbidity, mortality.

Secondary outcome

N.A.

Study description

Background summary

It concerns a study to investigate the relationship between personality, QoL and diurnal cortisol rhythm with regard to morbidity, prognosis and mortality in patient with breast cancer compared to patients with benign breast disease. Women included in the questionnaires-study will be asked to participate in this sub-study, the questionnaires will also be used in this substudy. The included women will be asked to collect saliva at home in three days at four time points at the baseline and after six months. The saliva collection will be done with a special cotton swab during one minute.

Study objective

The aim of the study will be to examine the relationship between personality, QoL and diurnal cortisol rhythm in women with a suspicion of breast cancer with regard to morbidity, prognosis and mortality.

Study design

We want to include at least 300 women in the study (breast cancer and benign) during a period of two years. Women with a benign diagnosis will be included as

comparison group. Based on a previous study, we know that approximately half of all patients receive a benign diagnosis. All women will be followed-up for two years.

Study burden and risks

N.A.

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

All women with a suspicion of breast cancer

Exclusion criteria

Recurrence of disease at baseline; poor expression in the dutch langage; dementia; history of psychiatric illness, using corticosteroid medication.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2007
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO Date:	20-02-2007
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	22-09-2008
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 21499
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL15659.008.06
OMON	NL-OMON21499