Chemosensitivity during phases of the menstrual cycle in breast cancer patients

Published: 26-03-2024
Last updated: 07-04-2024

To determine whether sensitivity towards NAC varies during different phases of the menstrual cycle in breast cancer patients.

Ethical review	Approved WMO
Status	Pending
Health condition type	Breast neoplasms malignant and unspecified (incl nipple)
Study type	Interventional

Summary

ID

NL-OMON56658

Source
ToetsingOnline

Brief title
Chemosense

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
breast cancer, triple negative

Research involving
Human

Sponsors and support

Primary sponsor: Nederlands Kanker Instituut
Source(s) of monetary or material Support: Onderzoeksgroep J. van Rheenen;NKI-AVL

Intervention

Keyword: breast cancer, neo adjuvant treatment, premenopausal, Triple negative

Outcome measures

Primary outcome

Primary endpoint of the study will be the rate of patients achieving a

pathological complete response (pCR rate) after neo-adjuvant treatment.

Secondary outcome

Secondary endpoints include: radiological and pathological reduction in tumor

size, residual cancer burden (RCB), recurrence-free interval (RFI) and

distant-recurrence free intervall (DRFI).

Study description

Background summary

In murine breast tumors, an increased sensitivity to neo-adjuvant chemotherapy (NAC) was observed when NAC was initiated at the estrus stage (follicular phase) compared to the diestrus stage (luteal phase). Moreover, preliminary data from a retrospective study in premenopausal patients with luminal and triple negative breast cancer (BC) showed similar results. To draw ultimate conclusions whether the menstrual cycle stage determines chemosensitivity in BC-patients and should guide treatment decisions, prospective validation in a larger patient cohort is warranted.
This study is the prospective cohort were these findings are validated.

Study objective

To determine whether sensitivity towards NAC varies during different phases of the menstrual cycle in breast cancer patients.

Study design

This study is a prospective, multicenter study in which a serum sample will be collected at the day of starting NAC treatment in breast cancer patients.

Intervention

Collection of a serum sample (8,5mL) at first day of NAC prior to chemotherapy

administration.

Study burden and risks

An extra serum sample of 8,5mL will be collected at day 1, prior to NAC administration. If possible, the extra sample will be collected simultaneously with regular blood withdrawal. Patients could experience minor side effects resulting from blood withdrawal including discomfort and small hematomas.

Contacts

Public
Nederlands Kanker Instituut

Plesmanlaan 121
Amsterdam 1066CX
NL
Scientific
Nederlands Kanker Instituut

Plesmanlaan 121
Amsterdam 1066CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

• Women with a new diagnosis of triple negative breast cancer who have not yet started systemic treatment.

• Patients with stage I-III disease, patient with locoregional recurrence who have not been treated with chemotherapy before.
• Aged < 60 years
• Women having a (regular) physiological menstrual cycle
• Patients who are assigned to receive neoadjuvant chemotherapy with or without immunotherapy, targeted therapy and endocrine therapy
• Patients must be systemic treatment naïve for current malignancy (e.g. no chemotherapy, hormonal therapy or targeted therapy)
• Signed written informed consent

Exclusion criteria

- current use of hormonal contraception or in the six weeks prior to start of neoadjuvant systemic treatment for breast cancer, either:
• Oral contraception (OAC)
• Hormonal intra-uterine device (IUD, Mirena)
• No ovarian function suppression to preserve fertility
• Other forms of hormonal contraception, including but not limited to: nuva-ring, Implanon, prikpil
- currently pregnant and / or breast feeding. In case of use of hormonal contraception or breast feeding in de last year: patients should have had at least 2 menstrual cycles since stopping hormonal contraception.
- IVF-trajectory for egg cell preservation prior to start of neoadjuvant systemic treatment
- Patients with known PCOS polycystic ovarian syndrome

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2024

Enrollment:	100
Type:	Anticipated

Ethics review

Approved WMO Date:	26-03-2024
Application type:	First submission
Review commission:	METC NedMec

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
ClinicalTrials.gov	NCTnummervolgt
CCMO	NL85173.041.23