Clinical evaluation of dried blood spots for the determination of tamoxifen and endoxifen levels

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Clinical evaluation of dried blood spot assay for the determination of tamoxifen and endoxifen levels

Ethical review	Approved WMO
Status	Will not start
Health condition type	Breast neoplasms malignant and unspecified (incl nipple)
Study type	Observational invasive

Summary

ID

NL-OMON37023

Source
ToetsingOnline

Brief title
Tamoxifen and endoxifen in DBS

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
breast cancer, mammacarcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Slotervaartziekenhuis
Source(s) of monetary or material Support: Laboratorium van de apotheek van het Slotervaartziekenhuis

Intervention

Keyword: Dried blood spots, Endoxifen, Tamoxifen, Therapeutic drug monitoring

Outcome measures

Primary outcome

Ratio of the concentration tamoxifen and endoxifen in serumsamples and

concentration of tamoxifen and endoxifen in dried blood spot samples.

Secondary outcome

not applicable

Study description

Background summary

Tamoxifen is a selective estrogen receptor modulator that is widely used for the treatment and prevention of breast cancer. Endoxifen, formed via N-desmethyltamoxifen and via 4-hydroxytamoxifen, is considered to be the most important metabolite. The steady state level of endoxifen is a proposed predictor of the clinical outcome of tamoxifen treatment. It is suggested that there is a minimum concentration threshold above which endoxifen is effective against the recurrence of breast cancer.
Current clinical practice is to measure tamoxifen and metabolite concentrations in serum, for therapeutic drug monitoring (TDM). The blood samples are drawn from patients when they visit the Antoni van Leeuwenhoek hospital. In order to make TDM less invasive for the patient, we set up a method to determine tamoxifen and endoxifen levels in dried blood spots (DBS). This enables sample collection by means of one fingerprick, as is previously shown for antiretroviral drugs.2,3 This technique allows patients to self-sample at home.
No relationship between DBS and serum concentrations of tamoxifen and endoxifen has been established yet. Since the target concentrations of endoxifen are determined in serum samples, there is a need to establish the correlation between DBS and serum concentrations. Therefore, the levels of tamoxifen and endoxifen have to be determined in simultaneously drawn DBS and serum samples of patients using tamoxifen.

Study objective

Clinical evaluation of dried blood spot assay for the determination of

tamoxifen and endoxifen levels

Study design

Patients are treated with tamoxifen on a dose according to the prescription of the physician. No further intervention is needed. A DBS sample will be obtained simultaneously with the serum sample that is obtained for regular clinical care.

Study burden and risks

not applicable

Contacts

Public
Slotervaartziekenhuis

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Treated with tamoxifen
- Age 18 years or older
- Able and willing to give informed consent
- Able and willing to undergo a fingerprick for dried blood spot sampling

Exclusion criteria

none

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	50
Type:	Anticipated

Ethics review

Approved WMO Date:	02-11-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	19-02-2014
Application type:	Amendment

Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)

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: 26648
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL41454.031.12
OMON	NL-OMON26648

Study results

Summary results
Trial never started