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

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Clinical evaluation of dried blood spot (DBS) assay, by determining the ratio between DBS and serum levels of tamoxifen and endoxifen and to investigate if patients can obtain useful DBS at home.

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

Summary

ID

NL-OMON40928

Source
ToetsingOnline

Brief title
Tamoxifen and endoxifen in DBS

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
breast cancer, mamma carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: Laboratorium apotheek AvL

Intervention

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

Outcome measures

Primary outcome

- Ratio of the DBS and serum concentrations of tamoxifen and endoxifen

Secondary outcome

- Percentage of patients that obtains a DBS by self-sampling at home

- Percentage of patients that provides DBS samples useful for analysis

Study description

Background summary

Tamoxifen, a selective estrogen receptor modulator, is widely used for the treatment and prevention of breast cancer. The steady state concentration of its most active metabolite, endoxifen, is a proposed predictor of tamoxifen efficacy. It is suggested that there is a minimum serum concentration above which endoxifen is effective against the recurrence of breast cancer. Current practice is to analyze tamoxifen and metabolite concentrations in serum, blood samples are collected when patients visit the Antoni van Leeuwenhoekhospital.

Study objective

Clinical evaluation of dried blood spot (DBS) assay, by determining the ratio between DBS and serum levels of tamoxifen and endoxifen and to investigate if patients can obtain useful DBS at home.

Study design

Patients treated with tamoxifen who undergo venapuncture are asked if they are willing to obtain a DBS sample at the same time. For the feasiblity part, patients are asked if they are willing to self-obtain a DBS sample through a fingerprick. They will be instructed at the Antoni van Leeuwenhoekhospital.

Study burden and risks

not applicable

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

- 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:	Pending
Start date (anticipated):	24-02-2014
Enrollment:	100
Type:	Anticipated

Ethics review

Approved WMO

Date:	02-11-2012
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

Approved WMO

Date:	19-02-2014
Application type:	Amendment
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	NL47958.031.14