Clinical evaluation of dried blood spots obtained from a fingerprick for the determination of tamoxifen and endoxifen levels

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26648

Source
NTR

Health condition

breast cancer, estrogen receptor positive

Sponsors and support

Primary sponsor: none
Source(s) of monetary or material Support: Bioanalytical Laboratory of Slotervaarthospital

Intervention

Outcome measures

Primary outcome

Ratio between endoxifen serum concentrations and endoxifen dried blood spot concentrations

Secondary outcome

N/A

Study description

Background summary

DBS samples to determine the pharmacokinetics of tamoxifen in a ‘real life’ cohort will be collected during a routine visit to the Antoni van Leeuwenhoek hospital where a serum sample is obtained as part of clinical care.

No relationship between DBS and serum concentrations has been established yet for tamoxifen and endoxifen. This would enable sample collection by means of a simple fingerprick. The DBS to serum ratio of tamoxifen and endoxifen has to be defined in simultaneously drawn DBS and serum samples of patients using tamoxifen.

Study objective

Tamoxifen and endoxifen serum concentrations are linearly related to DBS concentration

Study design

1 timepoint; a paired sample will be obtained a serum sample and a dried blood spot sample

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

1. Treated with tamoxifen;

2. Age minimum 18 years;

3. Able and willing to give written informed consent;

4. Able and willing to undergo a fingerprick voor dried blood spot sampling.

Exclusion criteria

None

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)

Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-03-2013
Enrollment:	50
Type:	Anticipated

Ethics review

Positive opinion

Date:	21-06-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 37023
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3881
NTR-old	NTR4042
CCMO	NL41454.031.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON37023

Study results

Summary results
N/A