Studying the influence of curcumin and piperine on tamoxifen exposure

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25193

Source
NTR

Brief title
ELDORADO

Health condition

Breast cancer

Sponsors and support

Primary sponsor: Erasmus MC
Source(s) of monetary or material Support: Erasmus MC

Intervention

Outcome measures

Primary outcome

To determine the influence of curcumin with or without piperine, in patients with breast cancer, on endoxifen plasma pharmacokinetics (AUC).

Secondary outcome

1. Other pharmacokinetic outcomes (i.e. clearance, Ctrough) and the tamoxifen/endoxifen ratio.

2. To evaluate plasma concentration levels of tamoxifen and other tamoxifen metabolites

3. To evaluate the incidence and severity of side-effects of treatment with tamoxifen in absence and presence of curcumin with or without piperine.

Study description

Background summary

In this study we try to determine the influence of curcumin with and without piperine on tamoxifen pharmacokinetics in patients with breast cancer.

Study objective

To determine the influence of curcumin and piperine on tamoxifen pharmacokinetics.

Study design

Pharmacokinetics will be taken at day 28, 56 and 84.

Intervention

Tamoxifen alone vs Tamoxifen and Curcumin vs Tamoxifen and Curcumin and Piperine

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

1. Age > 18 years

2. Histological or cytological confirmed diagnosis of breast cancer in patients with an indication for tamoxifen treatment.

3. WHO Performance Status <2

4. Able and willing to sign the Informed Consent Form prior to screening evaluations

5. Abstain from curry, grapefruit (juice), (herbal) dietary supplements besides curcumin, herbals, over-the-counter medication (except for paracetamol and ibuprofen).

6. Adequate baseline patient characteristics (complete blood count, and serum biochemistry which involves sodium, potassium, creatinin, calculation of creatinin clearance (MDRD), AST, ALT, gamma glutamyltranspeptidase (gamma-GT), lactate dehydrogenase (LDH), ALP, total bilirubin, albumin).

Exclusion criteria

A potential subject who meets any of the following criteria before study treatment will be excluded from participation in this study:

1. Pregnant or lactating patients.

2. Patients with known impaired drug absorption (e.g. gastrectomy and achlorhydria).

3. Use of other drugs, which are mainly dependent for their metabolism on CYP3A4 and CYP2D6.

4. Known serious illness or medical unstable conditions that could interfere with this study; requiring treatment (e.g. infection, bleedings, uncontrolled hypertension despite optimal medical management, HIV, hepatitis, organ transplants, kidney, cardiac and respiratory

diseases).

5. Bilirubin CTCAE grade 2 or higher, ASAT/ALAT CTCAE grade 2 or higher and grade 3 or higher in patients with liver metastasis. Renal function impairment CTCAE grade 2 or higher.

6. Symptomatic CNS metastases or history of psychiatric disorder that would prohibit the understanding and giving of informed consent.

7. Known hypersensitivity to any of the study drugs, study drug classes, or excipients in the formulation.

8. Patients on strong CYP3A4 or CYP2D6 inhibitors or inducers, P-gp substrates or medication or supplements which can interact with tamoxifen and curcumin are not eligible for the study.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-01-2017
Enrollment:	16
Type:	Actual

Ethics review

Positive opinion

Date:	16-01-2017
Application type:	First submission

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
NTR-new	NL5985
NTR-old	NTR6149
Other	METC Erasmus MC : MEC 16-679

Study results