Influence of an acidic beverage on the absorption of erlotinib

No registrations found.

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

Summary

ID

NL-OMON24483

Source
Nationaal Trial Register

Brief title
COLA-study

Health condition

lungcancer

Sponsors and support

Primary sponsor: Erasmus University Medical Center
Source(s) of monetary or material Support: Stichting de Merel

Intervention

Outcome measures

Primary outcome

Differences in erlotinib bioavailability during coca-cola intake vs. water intake (+/- PPI)

Secondary outcome

Toxicity of erlotinib

Study description

Background summary

PPI use during Erlotinib therapy decreases bioavailability of the latter. Since a PPI is often used during erlotinib therapy, this DDI confronts pharmacists and oncologists with major challenges. A profound solution for managing this DDI is not yet available.

A possible (and practical) way to by-pass the DDI between erlotinib and PPIs is to temporarily lower the stomach pH by taking erlotinib with an acidic beverage, such as Coca-Cola (pH=2,8). To determine the influence of the acidic beverage Coca-Cola, concomitantly taken with erlotinib (with or without a PPI), on erlotinib plasma pharmacokinetics compared to erlotinib concomitantly taken with water in cancer patients.

Study objective

PPI use during Erlotinib therapy decreases bioavailability of the latter. Since a PPI is often used during erlotinib therapy, this DDI confronts pharmacists and oncologists with major challenges. A profound solution for managing this DDI is not yet available.

A possible (and practical) way to by-pass the DDI between erlotinib and PPIs is to temporarily lower the stomach pH by taking erlotinib with an acidic beverage, such as Coca-Cola (pH=2,8).

Study design

N.a.

Intervention

To determine the influence of the acidic beverage Coca-Cola, concomitantly taken with erlotinib (with or without a PPI), on erlotinib plasma pharmacokinetics compared to erlotinib concomitantly taken with water in cancer patients.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age > 18 years

2. Use of Erlotinib monotherapy for at least 4 weeks

3. Subject is able and willing to sign the Informed Consent Form prior to screening evaluations

Exclusion criteria

1. Age < 18 years

2. Pregnant or lactating patients

3. Impossibility to take oral drugs

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):	25-04-2014
Enrollment:	28
Type:	Actual

Ethics review

Positive opinion

Date:	25-04-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 40431
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4320
NTR-old	NTR4540
CCMO	NL47466.078.14
OMON	NL-OMON40431

Study results

Summary results

van Leeuwen et al. Influence of the Acidic Beverage Cola on the Absorption of Erlotinib in Patients With Non-Small-Cell Lung Cancer. J Clin Oncol. 2016;34(12):1309-14