

Influence of an acidic beverage on the absorption of erlotinib

Gepubliceerd: 25-04-2014 Laatste bijgewerkt: 15-05-2024

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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24483

Bron

NTR

Verkorte titel

COLA-study

Aandoening

lungcancer

Ondersteuning

Primaire sponsor: Erasmus University Medical Center

Overige ondersteuning: Stichting de Merel

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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).

Onderzoeksopzet

N.a.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Erasmus MC Rotterdam – Daniel den Hoed Cancer Center
Department of Medical Oncology
Room G4-80
Ron H.J. Mathijssen
Groene Hilledijk 301

Rotterdam 3075 EA
The Netherlands
+31 (0)10 7041338, buzzer 229

Wetenschappelijk

Erasmus MC Rotterdam – Daniel den Hoed Cancer Center
Department of Medical
Oncology
 Room G4-80
Ron H.J. Mathijssen
Groene Hilledijk 301
Rotterdam 3075 EA
The Netherlands
+31 (0)10 7041338, buzzer 229

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Age < 18 years
2. Pregnant or lactating patients
3. Impossibility to take oral drugs

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	25-04-2014
Aantal proefpersonen:	28
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies	
Datum:	25-04-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 40431
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4320

Register

NTR-old

CCMO

OMON

ID

NTR4540

NL47466.078.14

NL-OMON40431

Resultaten

Samenvatting resultaten

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