Pharmacokinetics of the addition of an acidic beverage to posaconazole co-administered with a proton pump inhibitor in GVHD patients

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to investigate whether the bioavailability of posaconazole in graft-versus-host-disease (GVHD) patients, adversely affected by the coadministration of proton pump inhibitors (PPIs), can be restored by an acidic beverage

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON36495

Source
ToetsingOnline

Brief title
Pharmokinetics of cola addition to posaconazol and PPI in GVHD

Condition

- Other condition
- Fungal infectious disorders

Synonym
graft versus host ziekte

Health condition

graft versus host ziekte

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: acidic beverage, GVHD, posaconazol, proton pump inhibitor

Outcome measures

Primary outcome

difference in the bioavailability of posaconazole within patients on PPI with

or without concomitant use of the acidic beverage in hematopoietic stem-cell

transplantation patients with graft versus host disease.

Secondary outcome

To investigate whether the plasma concentrations of posaconazole in

graft-versus-host-disease (GVHD) patients, adversely affected by the

co-administration of proton pump inhibitors (PPIs), can be restored by the

acidic beverage.

Feasibility of concomitant administration of posaconazole and the acidic

beverage in GVHD patients. Plasma pharmacokinetics of posaconazole at the start

and at steady-state in graft-versus-host-disease (GVHD) patients concomitantly

using PPI.

Study description

Background summary

Antifungal prophylaxis with posaconazole in graft versus host disease patients may be less efficient due to interactions with PPIs, however this has not been tested in these patients. As posaconazole adsorption is pH dependent and adequate levels of posaconazole are important for its antifungal efficacy, a study that will evaluate the effects of the addition of an acidic beverage to posaconazole in allogeneic stem cell transplant patients co-treated with PPIs who have developed GVHD is proposed.

Study objective

to investigate whether the bioavailability of posaconazole in graft-versus-host-disease (GVHD) patients, adversely affected by the coadministration of proton pump inhibitors (PPIs), can be restored by an acidic beverage

Study design

a phase IV open label non randomized prospective comparative trial

Intervention

200mL of an acidic beverage (Coca Cola) will be administered concomitantly with posaconazole and PPI intake for a period of 7 days until a new steady state has been reached

Study burden and risks

The patients burden consists of a total of four days of blood sampling in the VU University medical center after posaconazole and PPI intake at day one (2-8 samples) and at steady state (reached after 6-7 days of posaconazole and PPI use, 1 sample), repeated after concomitant administration of an acidic beverage (200mL the acidic beverage) in a cross-over design.
In daily practice GVHD patients often use both posaconazole and PPI and because adequate levels of posaconazole are important for its antifungal efficacy, it seems highly relevant for this group to evaluate wether the interaction between posaconazole and PPI can be restored by an acidic beverage. As no essential change in treatment regimen will be made besides the addition of the acidic beverage and the main intervention will be blood sampling, risks are considered negligible.

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

*recipients of hematopoietic stem-cell transplantation (HSCT) with graft versus host disease (GVHD) using PPI
*start or use of posaconazole for invasive fungal infection (IFI) prophylaxis with concomitant PPI use for at least twelve days or one week when already using posaconazole

Exclusion criteria

*current clinical significant invasive fungal infection requiring treatment
*inability to sign informed consent
*inability to take oral medication
*allergy to posaconazole, PPI or the acidic beverage
*start or discontinuation of a CYP3a4 inhibitor or P-glycoprotein inducer during the study period
*age < 18 years
*grade II or more diarrhea, mucositis, vomiting

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-08-2011
Enrollment:	16
Type:	Actual

Ethics review

Approved WMO

Date:	07-04-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL34167.029.11