Confirming the pharmacological interaction between colchicine and 18F-choline PET

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Confirm the interaction between colchicine and the choline pathway as seen with FCH-PET.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Reproductive neoplasms male malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON38465

Source
ToetsingOnline

Brief title
Interaction between colchicine and choline PET

Condition

- Reproductive neoplasms male malignant and unspecified

Synonym
Prostate cancer

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: Onderzoeksfonds afdeling Nucleaire geneeskunde AVL.

Intervention

Keyword: Choline, Colchicine, Interaction, PET

Outcome measures

Primary outcome

The main study parameter is the uptake of FCH, as seen on PET, in the presence and absence of colchicine. The main study endpoint is the presence of an interaction, defined as colchicine induced absence of FCH transport from blood to tissues.

Secondary outcome

SUVmean of FCH uptake in various tissues, including e.g. tumor, liver, muscle, bone marrow and blood.

Study description

Background summary

We recently encountered a previously unknown pharmacological interaction in a patient, involving the apparent complete blocking of choline metabolism by colchicine (used to suppress inflammation in gout). This interaction resulted in a dramatically altered biodistribution of radiolabeled 18F-methyl-choline on positron emission tomography (FCH-PET), and prevented adequate molecular imaging for staging of prostate cancer in this patient. We identified colchicine as the likely cause of the distorted FCH-PET, as the biodistribution of FCH returned to normal after withdrawal of colchicine.

This interaction is considered clinically relevant, as it may result in suboptimal diagnosis and staging of cancer, and we now advise to withdraw colchicine prior to FCH-PET. However, the effect was demonstrated in only one patient, and it may have been patient-specific or influenced by other unknown factors. The current study aims to confirm the hypothesis that there is an interaction between colchicine and the choline pathway as seen with FCH-PET.

Colchicine may not be the only drug interfering with choline metabolism and FCH-PET. Other anti-mitotic drugs that target intracellular tubulin and result

in catabolic phosphatidylcholine metabolism, including e.g. docetaxel, paclitaxel and vincristine, may yield the same effects. It is imperative that we understand interactions for this group of drugs, in order to guide imaging and avoid diagnostic and treatment errors. In the present study we focus on the interaction between colchicine and FCH-PET. If this interaction is confirmed, we will continue with a second study focussed on the interactions between other tubulin targeting drugs and FCH-PET.

Study objective

Confirm the interaction between colchicine and the choline pathway as seen with FCH-PET.

Study design

A mono-centre interventional study, comparing the biodistribution of FCH in the absence and presence of colchicine. Patients receiving routine FCH-PET on clinical indication will be asked to undergo an additional FCH-PET scan after premedication with 1 mg colchicine per os.

Intervention

After the routine FCH-PET scan, an addition FCH-PET will be performed with premedication 1 mg colchicine per os.

Study burden and risks

Colchicine 1 mg per os is the normal start of treatment for an exacerbation of gout. No side effects or risks are known or expected from a single administration. Patients with pre-existent bone marrow or kidney disease will be excluded. FCH-PET(/CT) is a routine clinical imaging modality, with a duration of maximum 1 hour and a radiation burden of ~8 mSv, similar to other routine diagnostic procedures, without known or expected side effects, and without known or expected risks (especially in the evaluated group of patients with recurrent or metastasized cancer). The results of this study will have no impact on clinical decision-making or treatment for participating patients.

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

- Histopathologically proven prostate cancer
- Suspected of disease recurrence because of PSA relapse
- Scheduled for routine FCH-PET for restaging

Exclusion criteria

- Age < 18 years
- Mentally incompetent
- Pre-existent bone marrow disease (Hb<7.5 mmol/l, L<4.0x109/l, Tr<150x109/l)
- Pre-existent kidney disease (GFR<60 ml/min/1.7)
- Currently on chemotherapy

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2014
Enrollment:	5
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Colcrys
Generic name:	Colchicine
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	11-12-2013
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	20-05-2014
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	04-07-2014
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

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
EudraCT	EUCTR2013-003715-22-NL
CCMO	NL46218.031.13