

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

Published: 11-12-2013

Last updated: 23-04-2024

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

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Reproductive neoplasms male malignant and unspecified
<b>Study type</b>	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 additional 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**

### **Public**

Antoni van Leeuwenhoek Ziekenhuis

Plesmanlaan 121  
Amsterdam 1066 CX

NL

## **Scientific**

Antoni van Leeuwenhoek Ziekenhuis

Plesmanlaan 121

Amsterdam 1066 CX

NL

## **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<4.0x10<sup>9</sup>/l, Tr<150x10<sup>9</sup>/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