# Study on pharmacy prepared CDCA capsules

Published: 03-09-2021
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To investigate the pharmacokinetic profile of magistrally compounded CDCA capsules.

| | |
|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Endocrine disorders congenital |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON23443

**Source**
NTR

**Brief title**
CDCA-PK

### Condition

- Endocrine disorders congenital

**Health condition**

Cerebrotendinous Xanthomatosis

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Amsterdam UMC

### Intervention

**Explanation**

## Outcome measures

### Primary outcome

Pharmacokinetic profile of compounded CDCA capsules

### Secondary outcome

Effect on bile acid profile

# Study description

### Background summary

This study is an open label randomised single center cross-over study, to investigate the pharmacokinetics of compounded chenodeoxycholic acid capsules. The capsules will be compounded by the hospital pharmacy, and will via a cross-over design be compared to the commercial alternative. Healthy volunteers will take one 250 mg capsules of each, after which blood sampling will take place at various time points.

### Study objective

To investigate the pharmacokinetic profile of magistrally compounded CDCA capsules.

### Study design

2 visits with capsules intake followed by blood sampling, separated by a wash-out period of at least 1 week.

### Intervention

Chenodeoxycholic acid

# Contacts

**Public**
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**Scientific**

Amsterdam UMC
Natalja Bouwhuis

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# Eligibility criteria

**Age**
Adults (18-64 years)
Adults (18-64 years)
Elderly (65 years and older)
Elderly (65 years and older)

## Inclusion criteria

- Be 18 years of age or older - Be a male - Have a BMI between 18,5 and 30 kg/m2 - Able and willing to swallow the capsules - Able to undergo blood sampling for PK analysis - Able and willing to give written informed consent - Willing to follow the dietary restrictions - Able to complete the study

## Exclusion criteria

- Inability to give informed consent - Hypersensitivity to one of the components in either product - Smoking or use of other tobacco products - History of alcohol or drug abuse - Use of co-medication (as described in chapter 5.2) - Gastrointestinal disease that may impact the absorption - Metabolic or endocrine disease - Gallbladder disease and/or removal - Liver disease - Participation in another clinical trial during or in the 3 months prior to the study

# Study design

## Design

| | |
|---|---|
| Study phase: | 4 |
| Study type: | Interventional |
| Intervention model: | Crossover |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |

| | |
|---|---|
| Control: | Active |
| Primary purpose: | Treatment |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 27-09-2022 |
| Enrollment: | 12 |
| Type: | Actual |

### IPD sharing statement

**Plan to share IPD:** Undecided

**Plan description**
NA

## Ethics review

Approved WMO

| | |
|---|---|
| Date: | 01-11-2021 |
| Application type: | First submission |
| Review commission: | MEC Academisch Medisch Centrum (Amsterdam)<br>Kamer G4-214<br>Postbus 22660<br>1100 DD Amsterdam<br>020 566 7389<br>mecamc@amsterdamumc.nl |

## Study registrations

### Followed up by the following (possibly more current) registration

ID: 49918

Bron: ToetsingOnline
Titel:

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

No registrations found.

## In other registers

| Register | ID |
|---|---|
| NTR-new | NL9736 |
| Other | METC AMC : 2021_205 |
| EudraCT | 2021-003823-14 |
| CCMO | NL78477.018.21 |
| OMON | NL-OMON49918 |

# Study results

**Summary results**
NA