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
Nationaal Trial Register

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

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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) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 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