Pharmacokinetic cross-over study of compounded chenodeoxycholic acid

Published: 01-11-2021
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To investigate the pharmacokinetics of hospital pharmacy compounded CDCA capsules, compared to the commercial alternative.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Inborn errors of metabolism
Study type	Interventional

Summary

ID

NL-OMON49918

Source
ToetsingOnline

Brief title
CDCA-PK

Condition

- Inborn errors of metabolism

Synonym
cerebrotendinous xanthomatosis, CTX

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Vriendenloterij

Intervention

Keyword: CDCA, chenodeoxycholic acid, compounding

Outcome measures

Primary outcome

Pharmacokinetic parameters of hospital pharmacy compounded CDCA capsules,

compared to those of the commercial alternative.

Secondary outcome

Impact on other bile acids.

Study description

Background summary

Amsterdam UMC is treating its own patients with hospital pharmacy compounded CDCA capsules.

Study objective

To investigate the pharmacokinetics of hospital pharmacy compounded CDCA capsules, compared to the commercial alternative.

Study design

Single center, open label, cross-over study.

Intervention

CDCA 250 mg capsule.

Study burden and risks

Burden: 2 visits, 2 capsule-intakes, 2 times blood withdrawal
Estimated risk: minimal

Contacts

Public
Amsterdam UMC

Meibergdreef 9
Amsterdam 1105 AZ
NL
Scientific
Amsterdam UMC

Meibergdreef 9
Amsterdam 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
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
- moking or use of other tobacco products
- History of alcohol or drug abuse
- Use of co-medication
- 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

Medical products/devices used

Product type:	Medicine
Brand name:	CDCA
Generic name:	CDCA
Product type:	Medicine
Brand name:	CDCA
Generic name:	CDCA
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	01-11-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-11-2021
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

ID: 23443
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
EudraCT	EUCTR2021-003823-14-NL
CCMO	NL78477.018.21
OMON	NL-OMON23443