Exploratory Biomarker Study of Fatty Acid profiles in Healthy Volunteers and patients with Parkinson's Disease

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- To investigate the baseline profile and inter- and intra-subject within-day and between-day variability of the fatty-acid profiles including fatty-acid desaturation index (FA-DI) and PUFAs in the plasma of patients with Parkinson*s disease and...

Ethical review	Approved WMO
Status	Completed
Health condition type	Movement disorders (incl parkinsonism)
Study type	Observational invasive

Summary

ID

NL-OMON48468

Source
ToetsingOnline

Brief title
Fatty Acid profiles in Healthy Volunteers and Parkinson*s Disease

Condition

- Movement disorders (incl parkinsonism)

Synonym
Parkinson's Disease

Research involving
Human

Sponsors and support

Primary sponsor: Yumanity
Source(s) of monetary or material Support: Pharmaceutical Industry

Intervention

Keyword: Fatty Acid, Parkinson's disease

Outcome measures

Primary outcome

Fatty-acid profiles of the following fatty acids:,

* Saturated fatty acids in plasma including but not limited to: C16:0, C18:0

* Unsaturated fatty acids (MUFAs and PUFAs) in plasma including but not limited to: C16:1n7t, C16:1n9, C16:1n7, C18:1t, C18:1n9, C18:2n6t, C18:2n6, C18:3n6, C20:1n9, C18:3n3, C20:2n6, C20:3n6, C20:4n6, C20:5n3, C24:1n9, C22:4n6, C22:5n6, C22:5n3, C22:6n3

Fatty-acid desaturation index (FA-DI) in plasma will be calculated from the respective fatty acid profiles:

* Ratio between C16:1 and C16:0

* Ratio between C18:1 and C18:0

Secondary outcome

NA

Study description

Background summary

Yumanity is developing YTX-7739, an orally active, small molecule stearyl-CoA desaturase (SCD) inhibitor as a potential disease modifying therapy for patients with Parkinson*s disease. The investigational drug will be used in the CHDR1911 single dose study and subsequently in the CHDR1916 multiple dose study. Concomitant with initiation of Phase I studies of YTX-7739 in healthy volunteers, this exploratory study will evaluate fatty acid profiles in the

plasma of ten (10) patients with Parkinson*s disease and a cohort of ten (10) age- and sex-matched, healthy control subjects. The aim of this study is to examine baseline variability in C16 and C18 FA-DI and PUFAs, as well as broad changes in fatty-acid profiles, across subjects and assess within day and day-to-day variability in FA-DI and PUFAs within individual subjects over a period of 3 days. In addition, this study will explore differences between FA-DI and PUFAs in subjects with Parkinson*s disease as compared to healthy, age-matched controls. The data from this exploratory study will be used to determine the inter- and intra-subject variability of FA-DI and PUFAs and define appropriate timepoints and sampling intervals for FA-DI and PUFA determination in human subjects. Together, the results will inform design of the multiple ascending dose study of YTX-7739 in healthy volunteers and Parkinson*s patients.

Study objective

- To investigate the baseline profile and inter- and intra-subject within-day and between-day variability of the fatty-acid profiles including fatty-acid desaturation index (FA-DI) and PUFAs in the plasma of patients with Parkinson*s disease and healthy, age- and sex-matched control subjects.

Study design

This is an exploratory biomarker study of fatty acid profiles in healthy volunteers and individuals with Parkinson*s disease. A total of 20 subjects will undergo plasma sampling up to six times a day for three days.

Study burden and risks

This study requires collection of blood samples. The burden for the volunteer related to the study procedures is limited. All collections will be performed in a state-of-the-art clinical unit and medically supervised by qualified medical staff.

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

1. Healthy male or female subjects 35-80 years of age, inclusive. Healthy status is defined by absence of evidence of any active acute or chronic disease or illness following a detailed medical and surgical history, a complete physical examination including vital signs, 12-lead ECG, hematology, blood chemistry and urinalysis; deemed by the investigator to be clinically significant;
OR: Male or female subjects 40-75 years of age, with a confirmed diagnosis of Parkinson*s disease (Hoehn and Yahr grade 1-4) inclusive;
2. Body mass index (BMI) between 18-35 kg/m2, inclusive, and with a minimum weight of 50kg and maximum weight of 120kg;
3. Evidence of a personally signed, dated and witnessed informed consent document indicating that the subject has been informed of all pertinent aspects of the study;
4. Able and willing to give written informed consent and to comply with any and all study restrictions.

Exclusion criteria

1. Legal incapacity or inability to understand or comply with the requirements of the study;
2. Clinically significant findings as determined by medical history taking, physical examination, ECG and vital signs, which, in the opinion of the Investigator, does not allow study participation.

3. Any current, clinically significant, known medical condition other than Parkinson*s disease. Patients with a diagnosis of other neurological diseases, including Alzheimer*s disease, Huntington*s disease, vascular dementia, epilepsy, etc., will not be eligible for this study.
4. Have a urine drug screen detecting illicit drug(s) of abuse (morphine, benzodiazepines, cocaine, amphetamine, THC, methamphetamine, MDMA) or positive alcohol breath test at screening, with exception of positive urine drug screens caused by prescribed drugs, such as benzodiazepines for PD sleeping disorders;
5. Consume, on average, >8 units/day of (methyl)xanthines (e.g., coffee, tea, cola, chocolate);
6. History or clinical evidence of alcoholism or drug abuse;
7. Smoking of >5 cigarettes/day or equivalent;
8. Use of prescription, illicit or herbal medication within 7 days of study initiation, except for contraception or their current standard of care medications for the treatment of parkinsonism;
9. Simultaneous participation in a clinical trial more than 4 times in the previous year;
10. Being on a diet composed of relevantly altered amounts of fat, protein or carbohydrates that may affect triglyceride and fatty acid levels.
11. Loss of blood * 500ml within 3 months before screening

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	01-12-2019
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	31-10-2019
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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
CCMO	NL71599.056.19

Study results

Date completed:	05-02-2020
Results posted:	12-01-2022

First publication
07-01-2022