Trial Description

Title

An omics-based strategy using coenzyme Q10 in patients with Parkinson’s disease: Concept evaluation in a double-blind randomized placebo-controlled parallel group trial

Trial Acronym

MitoPD

URL of the trial

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Brief Summary in Lay Language

Clinical intervention with Conenzyme Q10 (period of 6 months) following an omics-based selection process

Brief Summary in Scientific Language

In this study, we will investigate the role of a six month lasting coenzyme Q10 treatment in Parkinson's disease patients. For this study, we will use a genetic stratification approach investigating homozygous PINK1/Parkin mutation carriers, heterozygous PINK1/Parkin mutation carriers, and two groups with a polygenic mitochondrial (omics+) and without a polygenic mitochondrial (omics-) profile (based on eight predefined SNPs). Besides common clinical endpoints (such as the improvement of motor symptoms as measured by the MDS-UPDRS-III) we will use phosphorus magnetic resonance spectroscopy to directly measure ATP and phosphocreatine (as surrogate markers for mitochondrial impairment in Parkinson's disease patients) levels to objectively measure bioenergetic improvements in vivo.

Do you plan to share individual participant data with other researchers?

[---]*

Description IPD sharing plan

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Organizational Data

- DRKS-ID: **DRKS00015880**
- Date of Registration in DRKS: **2018/11/15**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***

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- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **18-294 , Ethik-Kommission Universität zu Lübeck Medizinische Fakultät des Universitätsklinikums Schleswig-Holstein**

Secondary IDs

Health condition or Problem studied

- ICD10: **G20 - Parkinson disease**

Interventions/Observational Groups

- Arm 1: **156 mg QuinoMit Q10 fluid (equivalent dosage of 1200 mg Coenzym Q10) ubiquinon emulsion, 8 strokes tid (five hour gap between each intake, e.g. at 8 am 1pm, and 6pm) for an intervention period of 6 months**
- Arm 2: **placebo**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **patient/subject, investigator/therapist, assessor**
- Control: **Placebo**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **II**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Change of motor symptoms of Parkinson's disease patients following a 6 months intervention period. The primary endpoint will be the difference between the motor subscale of the revised "Unified Parkinson's Disease Rating Scale" (MDS-UPDRS) between baseline visit and after 6 months post-intervention.

Secondary Outcome

changes from the baseline visit in the following scales
1.) MDS-UPDRS-III motor subscale (after 3 and 9) months
2.) MDS-UPDRS-I (after 3, 6, and 9
months)
3.) Activities of daily living
MDS-UPDRS-II (after 3, 6, and 9 months)
4.) combined sum score based on the
"Timed up and Go-Test", "10-meter walk test", and "finger tapping task" (taken from the MDS-UPDRS-III) (after 3, 6, and 9 months)
5.) Quality of life bassed on the PDQ39 (after 3, 6, and 9 months)
6.) Depression as measured by the BDI II (after 3, 6, and 9 months)
7.) MDS-UPDRS-IV (after 3, 6, and 9 months)
8.) cognitive impairment as measured by Montreal Cognitive Assessment (after 3, 6, and 9 months)
9.)Fatigue Severity Scale (FSS) (after 3, 6, and 9 months)
10.) changes in brain metabolism (as measured via magnetic resonance spectroscopy) of PCr/inorganic phosphate (Pi) in Q10 treated patients (after 6 months)
11.) changes in brain metabolism (as measured via magnetic resonance spectroscopy) of ATP/Pi in Q10 treated patients (after 6 months)
12.) changes of structural MRI measures (based on DWI/DTI) (after 6 months)
13.) changes of structural MRI measures (based on measures of iron depositon/SWI) (after 6 months)
14.) changes of functional (resting state) MRI measures (of motor networks) (after 6 months)

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Klinik für Neurologie/Institut für Neurogenetik, Lübeck**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2018/12/15**
- Target Sample Size: **84**
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Target Sample Size: **84**

Monocenter/Multicenter trial: **Multicenter trial**

- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

PD diagnosis based on UK Brain Bank criteria

genotyping and assignment to regarding study group

stable PD mediaction (for at least 4 weeks)

age above or equal to 18 years

written informed consent

Exclusion criteria

comorbidities that impair giving informed consent (severe dementia [MMSE<24], psychosis, severe depression)

atypical or secondary parkinsonism

pregnancy, breastfeeding or current wish for pregnancy

no contraception, unless the patient is in her menopause

(self-)treatment with coenzyme Q10 up to 3 months before trial enrollment

known intolerance or allergy to conenzyme Q10

concomitant medication with thyroid drugs

concomitant medication with vitamine K anatgonists

concomitant medication with betablockers

epilepsy

structural brain damage (e. g. following stroke)

allergy to soy

concomitant participation in another clinical trial (besides pure questionnaire-based trials or vitamine K2 interventional trials) within the last 30 days prior to study enrollment

known severe liver or kidney disease

Addresses

- **Primary Sponsor**

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- **Contact for Scientific Queries**

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Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

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Status

- Recruitment Status: **Recruiting planned**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*