Trial Description

Title

Plasma kinetic of the concentration of D9- and D3-choline and their metabolites in the plasma of male adults after administration of four D9-marked choline supplements

Trial Acronym

CHOLINORAL IIb

URL of the trial

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Brief Summary in Lay Language

Comparison of the plasma kinetics of different D9-labeled choline components in tracer dosage in male adults

Brief Summary in Scientific Language

To date clinical pilot studies on choline supplementation using choline chloride were performed in preterm infants and Cystic Fibrosis (CF) patients. In both patient groups this resulted in (1.) a normalization of plasma choline concentrations, and in CF patients lung function was improved and increased liver fat reduced. (3) In both groups, single labeling with D9-choline chloride resulted in a better understanding of choline and phospholipid metabolism. In this study different candidates of optimized choline supplementation will be given to healthy adult males, in form of a single oral tracer dosage of the D9-labeled analogues of organic esters (D9-alpha-glycerophosphorylcholine [D9-alpha-GPC], D9-phosphorylcholine and D9-phosphatidylcholine [D9-PC]), compared to the free D9-choline salt (D9-choline chloride). In plasma and erythrocyte membranes, D9-enrichment of choline and its deuterated metabolites will be determined over time, to assess differences in the intermediary metabolism of the individual components.

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

No

Description IPD sharing plan

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Organizational Data

- DRKS-ID: **DRKS00020498**

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- Date of Registration in DRKS: **2020/01/22**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **322/2019B01 , Ethik-Kommission an der Medizinischen Fakultät der Eberhard-Karls-Universität und am Universitätsklinikum Tübingen**

Secondary IDs

Health condition or Problem studied

- ICD10: **E63.8 - Other specified nutritional deficiencies**

Interventions/Observational Groups

- Arm 1: **[D9-Methyl]-Choline chloride 3.6 mg/kg, blood samples 5 min before and 0,5h, 1h, 1,5h, 2h, 2,5h, 3h, 4h, 5h, 6h, 9h, 24h, 33h, 48h, 3d, 4d und 7d after intake, wash-out phase of 6 weeks.**
- Arm 2: **[D9-Methyl]-Phosphorylcholine chloride-Ca-Salz 6.4 mg/kg, blood samples 5 min before and 0,5h, 1h, 1,5h, 2h, 2,5h, 3h, 4h, 5h, 6h, 9h, 24h, 33h, 48h, 3d, 4d und 7d after intake, wash-out phase of 6 weeks.**
- Arm 3: **[D9-methyl]-alpha-GPC 6.4 mg/kg, blood samples 5 min before and 0,5h, 1h, 1,5h, 2h, 2,5h, 3h, 4h, 5h, 6h, 9h, 24h, 33h, 48h, 3d, 4d und 7d after intake, wash-out phase of 6 weeks.**
- Arm 4: **[D9-Methyl]-POPC 18.6 mg/kg, blood samples 5 min before and 0,5h, 1h, 1,5h, 2h, 2,5h, 3h, 4h, 5h, 6h, 9h, 24h, 33h, 48h, 3d, 4d und 7d after intake, wash-out phase of 6 weeks.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Other**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Active control (effective treament of control group)**

Study Type: **Interventional**

Study Type Non-Interventional: **[---]***

Allocation: **Other**

Blinding: **[---]***

Who is blinded: **[---]***

Control: **Active control (effective treament of control group)**

- Purpose: **Basic research/physiological study**
- Assignment: **Crossover**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

AUC of the D9-choline plasma concentration

Secondary Outcome

1. AUC of D9-Batain
2. AUC of D9-PC
3. Time until the maximum plasma concentration of D9-choline is reached
4. Time until the maximum plasma concentration of D9-choline derivates is reached
5. Velocity of increase and decrease of plasma concentrations during 7 days
6. Distribution of the labeling to the different D9-choline labeled metabolites

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Tübingen**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2020/03/01**
- Target Sample Size: **6**
- Monocenter/Multicenter trial: **Monocenter trial**

Planned/Actual: **Planned**

(Anticipated or Actual) Date of First Enrollment: **2020/03/01**

Target Sample Size: **6**

Monocenter/Multicenter trial: **Monocenter trial**

- National/International: **National**

Inclusion Criteria

- Gender: **Male**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

1. >= 18 years
2. male

Exclusion criteria

1. chronic alcohol abuse
2. acute diseases
3. chronic diseases that change the lipid and cholin metabolism (i.e. untreated Hypothyreosis, Hyperthyreosis, diseases of the lipid metabolism, diseases of the digestive tract and his glands, diabetes, pancreatitis, chronic kidney diseases, ventricular funcitonal limitations that influence the liver function)
4. vegan diet
5. nutritional supplements containing choline

Addresses

- **Primary Sponsor**

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Geissweg 3
72076 Tübingen
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **www.medizin.uni-tuebingen.de**

- **Contact for Scientific Queries**

Universitätsklinik für Kinder- und Jugendheilkunde
Mr. Prof. Wolfgang Bernhard

Contact for Scientific Queries

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Sources of Monetary or Material Support

- **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

Hipp-Werk Georg Hipp
Georg-Hipp-straße 7
85276 Pfaffenhofen
Germany

Telephone: **+49(0)8441-757-129**
Fax: **+49(0)8441-757-777-129**
E-mail: **[---]***
URL: **http://www.hipp.de**

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.*