Trial Description

Title

Increase and decrease of the concentration of choline and choline metabolites in the plasma of male adults after the administration of 4 different unmarked choline supplements

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Comparison of the plasma kinetics of different choline components in adequate intake 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, (2.) 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 candidate substances of an optimized choline supplementation will be investigated in healthy adult males. These candidates are physiologic organic choline esters (alpha-glycerophosphorylcholine [alpha-GPC] and egg phosphatidylcholine [PC]) in comparison with free choline salts (choline chloride, choline bitartrate). In plasma and erythrocyte membranes the concentrations of choline and its metabolites will be assessed to define differences of these components with respect to their plasma kinetics.

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

No

Description IPD sharing plan

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Organizational Data

- DRKS-ID: **DRKS00020454**
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Date of Registration in DRKS: **2020/01/17**

- 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.: **322/2019BO1 , 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: **Choline chlorid 740mg , blood samples 0,1h before and 1h, 1,5h, 2h, 2,5h, 3h, 4h, 5h, 6h, 9h und 24h Std. after intake, wash-out phase of one week**
- Arm 2: **Choline bitartrate 1336mg, blood samples 0,1h before and 1h, 1,5h, 2h, 2,5h, 3h, 4h, 5h, 6h, 9h und 24h Std. after intake, wash-out phase of one week**
- Arm 3: **alphaGCP 1358mg, blood samples 0,1h before and 1h, 1,5h, 2h, 2,5h, 3h, 4h, 5h, 6h, 9h und 24h Std. after intake, wash-out phase of one week**
- Arm 4: **Egg phosphatidylcholine 4018mg, blood samples 0,1h before and 1h, 1,5h, 2h, 2,5h, 3h, 4h, 5h, 6h, 9h und 24h Std. after intake, wash-out phase of one week**

Characteristics

- 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**

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 choline plasma concentration 0h-24h

Secondary Outcome

1. Change of plasma concentration of choline within 24h
2. Change of plasma concentrations of metabolites within 24h

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Tübingen**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2020/01/08**
- 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 choline 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 functional limitations that influence the liver function)
4. vegan diet
5. nutritional supplements containing choline

Addresses

- **Primary Sponsor**

  Universitätsklinikum Tübingen
  Geissweg 3
  72076 Tübingen
  Germany

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

- **Contact for Scientific Queries**

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- **Contact for Public Queries**

  Universitätsklinik für Kinder- und Jugendheilkunde

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URL: **[---]***

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 ongoing**
- 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.*