Trial Description

Title

Increase and decrease of the concentration of choline derivates in the plasma of preterm infants after the administration of unlabeled choline supplements

Trial Acronym

CHOLINORAL IId

URL of the trial

[---]*

Brief Summary in Lay Language

Comparison of the plasma kinetics of different choline components in adequate intake dosage in preterm infants

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 candidate substances of an optimized choline supplementation will be investigated in preterm infants. 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

[---]*

Organizational Data

- DRKS-ID: **DRKS00020505**
- Date of Registration in DRKS: **2020/01/23**

DRKS-ID: **DRKS00020505**
Date of Registration in DRKS: **2020/01/23**

- 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: **Choline chloride (40mg/kg/d), blood samples at up to 72h before as well as 3 or 6h after start and 3 or 6h after end of administration for two days.**
- Arm 2: **Choline bitartrate (72mg/kg/d), blood samples at up to 72h before as well as 3 or 6h after start and 3 or 6h after end of administration for two days.**
- Arm 3: **alpha-GPC (73.5mg/kg/d), blood samples at up to 72h before as well as 3 or 6h after start and 3 or 6h after end of administration for two days.**
- Arm 4: **Egg phosphatidylcholine (217mg/kg/d), blood samples at up to 72h before as well as 3 or 6h after start and 3 or 6h after end of administration for two days.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Active control (effective treament of control group)**
- Purpose: **Basic research/physiological study**
- Assignment: **Parallel**

Study Type: **Interventional**

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

Allocation: **Randomized controlled trial**

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

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

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

Purpose: **Basic research/physiological study**

Assignment: **Parallel**

- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

AUC of the choline plasma concentration 0h-54h

Secondary Outcome

1. Change of plasma concentration of cholin between 3 and 54h
2. Change of plasma concentrations of metabolites between 3 and 54h

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: **32**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **no minimum age**
- Maximum Age: **40 Days**

Additional Inclusion Criteria

1. Gestational age at birth 28-32 weeks
2. full enteral feeding
3. no acute diseases

Exclusion criteria

1. Growth retardation / birth weight < 3rd percentile
2. genetic diseases
3. Diseases, that change the lipid metabolism, especially the gastro intestinum (i.e. stoma, exocrine pancreas insufficience, cholestase), systemic glucocorticoidtherapy, kidney insufficience (creatinine >1.5mg/dl), ventricular funcitonal limitations that influence the liver function
4. no informed consent of both parents

Addresses

- **Primary Sponsor**

  Universitätsklinikum Tübingen
  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
  Calwerstraße 7
  72076 Tübingen
  Germany

  Telephone: **07071-2986377**
  Fax: **07071-293969**
  E-mail: **wolfgang.bernhard at med.uni-tuebingen.de**
  URL: **[---]***

- **Contact for Public Queries**

  Universitätsklinik für Kinder- und Jugendheilkunde

Contact for Public Queries

Universitätsklinik für Kinder- und Jugendheilkunde
Mr. Prof. Wolfgang Bernhard
Calwerstraße 7
72076 Tübingen
Germany

Telephone: **07071-2986377**
Fax: **07071-293969**
E-mail: **wolfgang.bernhard at med.uni-tuebingen.de**
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 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.*