

## Trial Description

### Title

**Plasma kinetic of the concentration of D9-choline derivates in the plasma of preterm infants after administration of four D9-labeled choline supplements**

### Trial Acronym

**CHOLINORAL IIc**

### URL of the trial

[---]\*

### Brief Summary in Lay Language

**Comparison of the plasma kinetics of different D9-labeled choline components in tracer 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 the different candidates of optimized choline supplementation will be given to preterm infants, 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

[---]\*

## Organizational Data

■ DRKS-ID: **DRKS00020502**

■



DRKS-ID: **DRKS00020502**

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 (3.6mg/kg), blood samples at 6 and 48h or 12 and 60h (two blood samples per infant at clinically indicated time points)**
- Arm 2: **[D9-Methyl]-Phosphorylcholine chloride Ca-salt (6.4mg/kg), blood samples at 6 and 48h or 12 and 60h (two blood samples per infant at clinically indicated time points)**
- Arm 3: **[D9-Methyl]-alpha-GPC (6.4mg/kg), blood samples at 6 and 48h or 12 and 60h (two blood samples per infant at clinically indicated time points)**
- Arm 4: **[D9-Methyl]-POPC (18.6mg/kg), blood samples at 6 and 48h or 12 and 60h (two blood samples per infant at clinically indicated time points)**

## Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]\*
- Allocation: **Randomized controlled trial**
- Blinding: [---]\*
- Who is blinded: [---]\*
- Control: **Active control (effective treatment 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 treatment 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 D9-Betain**

### Secondary Outcome

1. **Maximum of the plasma concentration of D9-Betain**
2. **Maximum of the plasma concentration of D9-PC**
3. **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: **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 / birthweight < 3rd percentile**
- 2. genetic diseases**
- 3. Diseases, that change the lipid metabolism, especially the gastro intestinum (i.e. stoma, exocrine pancreas insufficiency, cholestase), systemic glucocorticoidtherapy, kidney insufficiency (creatinine >1.5mg/dl), ventricular functional 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](http://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@med.uni-tuebingen.de](mailto:wolfgang.bernhard@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.