



PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Analysis of copper- and zink-content of breast milk in women suffering from Wilson's disease

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Assessing zinc- and copper-content in the breast milk of women suffering from Wilson's disease

Brief Summary in Scientific Language

Mothers suffering from Wilson's disease collect breast milk for 24 h every month for three months. The milk's copper and zinc-content will be measured and the baby's intake of the trace minerals will be calculated.

Organizational Data

- DRKS-ID: **DRKS00015032**
- Date of Registration in DRKS: **2019/08/28**
- 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.: **212-14 , Ethik-Kommission der Medizinischen Fakultät der Ludwig-Maximilians-Universität München**

Secondary IDs

Health condition or Problem studied



- ICD10: **E83.0 - Disorders of copper metabolism**

Interventions/Observational Groups

- Arm 1: **Mothers pump and collect all milk over a 24-hour period at 4-6, 8-10 and 12-14 weeks after birth. Milk is expressed by pump into new glas containers. Both the pump-set and the Containers are flushed with aqua dest. prior to use. Mothers put the milk into the freezer and store it at home until transfer to the lab. The Infant ist fed formula at the days of milk sampling. The total amount of consumed milk is noted in a protocol. Analyses for copper and zinc contend are done at the Institute for Laboratory Medicine of Munich University Hospital. The copper and zink content, the amount of expressed milk and the amount of milk consumed by the infant let us calculate the infant's intake of the trace minerals copper and zinc. The calculated intake will be compared to the recommended daily intake (according to ESPHAGAN recommendations, Koletzko, 2005).**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Single arm study**
- Blinding: [---]*
- Who is blinded: [---]*
- Control: **Uncontrolled/Single arm**
- Purpose: **Basic research/physiological study**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

An analysis of the copper- and zinc-concentration in breastmilk as well as a calculation of the infant's copper and zinc intake at the days of milk sampling had he/she been exclusively breastfed will be done in this study.

Secondary Outcome

[---]*

Countries of recruitment

- **DE Germany**



Locations of Recruitment

- University Medical Center **Perinatalzentrum Großhadern, München**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2016/09/24**
- Target Sample Size: **5**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

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

Additional Inclusion Criteria

Breastfeeding mothers, Diagnosis of Wilson's disease

Exclusion criteria

Problems with breastfeeding

Addresses

■ Primary Sponsor

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■ Contact for Scientific Queries

Contact for Scientific Queries

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■ **Contact for Public Queries**

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Sources of Monetary or Material Support

■ **Institutional budget, no external funding (budget of sponsor/PI)**

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Status

■ Recruitment Status: **Recruiting ongoing**

■ Study Closing (LPLV): [---]*

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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.*