

Trial Description

Title

Protect thumb-sucking and nail-biting from chronic inflammatory bowel diseases?

Trial Acronym

thumb-IBD

URL of the trial

[---]*

Brief Summary in Lay Language

The reasons for the origin of a chronic inflammatory disease (IBD) are very varied and are often unsettled in particular cases.

In a new study from New Zealand it was proved, that thumb-sucking and nail-biting in the infancy leads for a reduction of the risk of e.g. asthma and hay fever. Nevertheless, a possible risk reduction for an IBD was not examined.

It is sure: both behaviour patterns raise the biodiversity of bacteria of the flora of the mouth. Hence, it seems possible, that thumb-sucking and nail-biting raise also the variety of the childish intestinal flora and thereby decrease the risk for the origin of an IBD.

Brief Summary in Scientific Language

Thumb-sucking and nail-biting raise the proof likelihood from enterobacteriaceae and intestinal parasite in the mouth. Hence, it seems possible that thumb-sucking and nail-biting also raise the variety of childish intestinal microbiome. Topically it was proved first that thumb-sucking and nail-biting in the infancy leads to a reduction of the risk of an atopic sensitization at the adult's age (Lynch et Al.:Pediatrics in 2016).

Hence, it is interesting to examine first in a case control study, whether thumb-sucking and nail-biting protect also against IBD.

Organizational Data

- DRKS-ID: **DRKS00011549**
- Date of Registration in DRKS: **2017/01/04**
- Date of Registration in Partner Registry or other Primary Registry: [---]*
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **No approval required according to EC**
- (leading) Ethics Committee Nr.: **4922-09/16/16 , Ethikkommission der Friedrich-Schiller-Universität Jena an der Medizinischen Fakultät**



Secondary IDs

Health condition or Problem studied

- ICD10: **K50 - Crohn disease [regional enteritis]**
- ICD10: **K51 - Ulcerative colitis**

Interventions/Observational Groups

- Arm 1: **IBD patients < 40 years are questioned by a 4 page questionnaire about the hygienic conditions, thumb-suckings, nail-biting, breast-feeding etc. in the childhood to different times.**
- Arm 2: **Siblings of IBD patients without IBD are questioned by a questionnaire about the hygienic conditions, thumb-suckings, nail-biting, breast-feeding etc. in the childhood to different times.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Non-randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Other**
- Purpose: **Prevention**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Relation between thumb-sucking or nail-biting in the pre-school age and/or at the young adult's age and the reduction of IBD risk. The data are raised by a patient's questionnaire.

Secondary Outcome

Relation between hygiene-related risk factors of IBD (use of disinfectants, animal contact, breast-feeding) and the reduction of IBD risk. The data are raised by a patient's questionnaire.



Countries of recruitment

- DE **Germany**
- AT **Austria**

Locations of Recruitment

- University Medical Center **Verschiedene**
- Doctor's Practice **verschiedene**
- Medical Center **verschiedene**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2017/01/02**
- Target Sample Size: **2050**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

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

Additional Inclusion Criteria

IBD, contact to a siblings, contact to a reference person from childhood

Exclusion criteria

None

Addresses

- **Primary Sponsor**
CED Service GmbH
Mr. Klaus Fitzke



Primary Sponsor

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Sources of Monetary or Material Support

■ **Private sponsorship (foundations, study societies, etc.)**

German IBD Study Group

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

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Status

- Recruitment Status: **Recruiting complete, follow-up continuing**
- Study Closing (LPLV): **2019/06/30**

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.