Trial Description

Title

Probiotics-Study – Examination of the effect of the regular ingestion of the probiotic Lactobacillus reuteri on the health of male adults in a workplace setting

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Background: Common colds and gastro-intestinal diseases lead to increasing times of absence of employees in winter months. These diseases lead to high costs for the employer and higher stress-levels for healthy employees.

Purpose: A preventive effect of the regular ingestion of the probiotic Lactobacillus reuteri would lead to a decreasing average number of days of absence due to infections of the respiratory and the digestive system and thereby to considerable savings for the employer. Additionally a preventive effect would improve the health condition of the employees.

Method: Participants will be randomly divided into two groups. One group will receive the probiotic, the other group will receive placebo. We expect that these two groups differ in the frequency of symptoms of common colds and gastro-intestinal diseases and thereby in the number of days of absence of the employees.

Participants: Participants are employees of a steel producing company in Bremen, Germany.

Hypothesis: We want to evaluate if the regular ingestion of the probiotic Lactobacillus reuteri has an effect on the number of days of absence of the employees.

Brief Summary in Scientific Language

The current study is a double-blind randomised placebo-controlled trial.

Research question:
Does the regular ingestion of the probiotic Lactobacillus reuteri improve workplace healthi-ness for male employees in the steel industry?

Null hypothesis: The regular ingestion of the probiotic Lactobacillus reuteri has no effect on the number of days of absence of the employees.
Alternative hypothesis: The regular ingestion of the probiotic Lactobacillus reuteri has an effect on the number of days of absence of the employees.

Intervention:
Participants in group A will be asked to take one chewable tablet with Lactobacillus reuteri (100000000 CFU) per day over a period of 90 days.
Participants in group B will be asked to take a placebo tablet in the same period of 90 days.

Primary outcome is the number of days of absence reported by the participants in the diary.
Participants also report any symptoms of infections of the respiratory and the digestive system. By this means it is possible to examine frequency and duration of the symptoms as secondary outcomes.

The basic population consists of 671 male employees from two defined working areas at ArcelorMittal Bremen. The sample consists of at least 234 volunteers (circa 117 persons in group A and B).

Data evaluation is based on the German guidelines for “Good Epidemiological Practice” (GEP) and the “intention to treat” concept. The software “SPSS” will be used for statistical analyses. The t-test will be used to analyse the primary outcome. Descriptive analyses are planned for the secondary outcomes. Influences of working conditions, lifestyle habits and health situations on the secondary outcomes can be shown via four-field matrixes and chi-square tests. No interim analyses are planned.

Organizational Data

- DRKS-ID: **DRKS00004430**
- Date of Registration in DRKS: **2012/11/07**
- 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.: **368 , Ethik-Kommission der Ärztekammer Bremen**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1135-9064**

Health condition or Problem studied

- ICD10: **J00 - Acute nasopharyngitis [common cold]**
- ICD10: **K52.9 - Noninfective gastroenteritis and colitis, unspecified**

Interventions/Observational Groups

- Arm 1: **One chewable tablet ("BioGaia ProTectis") with the probiotic Lactobacillus reuteri (at least 100000000 CFU) per day over a period of 90**

days.

- Arm 2: **Placebo tablet in the same period of 90 days.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **patient/subject, investigator/therapist, data analyst**
- Control: **Placebo**
- Purpose: **Prevention**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Primary outcome is the number of days of absence reported by the participants in the diary.

Secondary Outcome

Participants report in a diary format any symptoms of infections of the respiratory and the digestive system. By this means it is possible to examine frequency and duration of the symptoms as secondary outcomes.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- other **ArcelorMittal Bremen GmbH, Bremen**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2012/11/29**
- Target Sample Size: **234**

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(Anticipated or Actual) Date of First Enrollment: **2012/11/29**

Target Sample Size: **234**

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

Inclusion Criteria

- Gender: **Male**
- Minimum Age: **18 Years**
- Maximum Age: **65 Years**

Additional Inclusion Criteria

No retirement during the study period

Exclusion criteria

**Age (younger than 18 or older than 65), sex (female), retirement during the study period,
pre-existing conditions (diabetes, cancer, abscesses, pancreatitis, HIV, organ transplantation)**

Addresses

- **Primary Sponsor**

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Sources of Monetary or Material Support

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

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Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2013/05/19**

Trial Publications, Results and other documents

- Paper **Schröder C, Schmidt S, Garbe E, Röhmel J, Giersiepen K (2015): Effects of the regular intake of the probiotic Lactobacillus reuteri (DSM 17938) on respiratory and gastrointestinal infections in a workplace setting: a double-blind randomized placebocontrolled trial. BMC Nutrition 2015,1:3**

** 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.*