ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: November 21, 2016

ClinicalTrials.gov ID: NCT02968498

Study Identification

Unique Protocol ID:	Lact-001-CEN
Brief Title:	Blood Glucose Response After Oral Intake of Lactulose in Healthy Volunteers
Official Title:	Blood Glucose Response After Oral Intake of Lactulose in Healthy Volunteers
Secondary IDs:	

Study Status

Record Verification:	November 2016
Overall Status:	Not yet recruiting
Study Start:	November 2016
Primary Completion:	February 2017 [Anticipated]
Study Completion:	February 2017 [Anticipated]

Sponsor/Collaborators

Sponsor:	Fresenius Kabi
Responsible Party:	Sponsor
Collaborators:	

Oversight

FDA Regulated?:	No
IND/IDE Protocol?:	No
Review Board:	Approval Status: Approved Approval Number: F-2016-098 Board Name: Ethics Commission Board Affiliation: Landesärztekammer Baden-Württemberg Phone: +49 711 76 989 Email: ethikkommission@laek-bw.de
Data Monitoring?:	No
Plan to Share IPD?:	No
Oversight Authorities:	Germany: Ethics Commission

Study Description

Brief Summary: Prospective, open, mono-center, randomized, two part study with 4-way cross-over design in each study part.

The objective of the study is to investigate blood glucose levels after oral intake of defined amounts of lactulose.

Detailed Description:

Conditions

Conditions: Blood Glucose

Keywords: Blood glucose level
Oral intake
Lactulose
Healthy volunteers

Study Design

Study Type: Interventional

Primary Purpose: Basic Science

Study Phase: N/A

Intervention Model: Crossover Assignment

Number of Arms: 2

Masking: Open Label

Allocation: Randomized

Endpoint Classification: Pharmacokinetics Study

Enrollment: 24 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions
Active Comparator: Study arm 1 Lactulose crystals 10 g vs lactulose crystals 20 g vs oral glucose 20 g vs still water	Dietary Supplement: Lactulose crystals 10 g White or almost white crystalline powder used as food ingredient. The products will be provided in sachets to be dissolved in 250 mL water. Dietary Supplement: Lactulose crystals 20 g White or almost white crystalline powder used as food ingredient. The products will be provided in sachets to be dissolved in 250 mL water. Dietary Supplement: Oral glucose 20 g White crystalline powder used as food ingredient. To standardise for 20 g glucose, 22 g glucose monohydrate will be used. The products will be provided in sachets to be dissolved in 250 mL water. Other Names: • glucose monohydrate Dietary Supplement: Still water

Arms	Assigned Interventions
	Still water will be used. Water from the same source will be also used to dissolve investigational and control products.
Active Comparator: Study arm 2 Lactulose liquid 10 g vs lactulose liquid 20 g vs oral glucose 20 g vs still water	Dietary Supplement: Lactulose liquid 10 g Clear, viscous liquid, colourless or pale brownish-yellow liquid syrup (solution). The products will be provided in sachets to be dissolved in 250 mL water. Dietary Supplement: Lactulose liquid 20 g Clear, viscous liquid, colourless or pale brownish-yellow liquid syrup (solution). The products will be provided in sachets to be dissolved in 250 mL water. Dietary Supplement: Oral glucose 20 g White crystalline powder used as food ingredient. To standardise for 20 g glucose, 22 g glucose monohydrate will be used. The products will be provided in sachets to be dissolved in 250 mL water. Other Names: • glucose monohydrate Dietary Supplement: Still water Still water will be used. Water from the same source will be also used to dissolve investigational and control products.

Outcome Measures

Primary Outcome Measure:

1. Capillary blood glucose levels as incremental area under the curve (iAUC) above baseline (iAUC(0-180min))
   [Time Frame: 0-180 min] [Safety Issue: No]

Secondary Outcome Measure:

2. Maximum blood glucose concentration (Cmax)
   [Time Frame: 0-180 min] [Safety Issue: No]
3. Maximum increase of blood glucose concentration (Max_increase)
   [Time Frame: 0-180 min] [Safety Issue: No]
   Cmax minus baseline value
4. Relative maximum increase of blood glucose concentration(Max_increase rel)
   [Time Frame: 0-180 min] [Safety Issue: No]
   Cmax / baseline value
5. Time to reach maximum blood glucose concentration (Tmax)
   [Time Frame: 0-180 min] [Safety Issue: No]
6. First time to reach baseline again after increase or decrease in blood glucose (Tbaseline)
   [Time Frame: 0-180 min] [Safety Issue: No]
7. Total area under curve from 0 to 180 min for blood glucose concentration (AUC(0-180min))
   [Time Frame: 0-180 min] [Safety Issue: No]
8. Baseline corrected area under curve from 0 to 180 min for blood glucose concentration (AUCbase_c(0-180min))
   [Time Frame: 0-180 min] [Safety Issue: No]
   Area under curve from 0 to 180 min minus baseline*180min
9. Adverse events (AEs)
   [Time Frame: After screening till study day 22 (+24 hours)] [Safety Issue: Yes]
10. Gastrointestinal tolerability (assessed by subject's questionnaire)
    [Time Frame: 180 min] [Safety Issue: No]

11. Gastrointestinal tolerability (assessed by subject's questionnaire)
[Time Frame: 24 hours post-dose] [Safety Issue: No]

Eligibility

Minimum Age:	18 Years
Maximum Age:	65 Years
Gender:	Both
Accepts Healthy Volunteers?:	Yes
Criteria:	Inclusion Criteria:

- Healthy volunteers
- Age: 18-65 years
- Approx. 3-5 bowel movements per week
- Caucasian
- Availability and presence in the trial unit for approx. 4 hours/ week for 4 times in a row with approx. 1 week of washout in between
- Signed informed consent form

Exclusion Criteria:

- Known (family) history of diabetes mellitus or use of anti-hyperglycaemic drugs or Insulin
- Clinically relevant renal or hepatic disease, liver enzymes > 10% above reference range
- Fasting blood glucose > 100 mg/dL or HbA1c outside of reference range
- Total cholesterol > 250 mg/dL or triglycerides > 150 mg/dL
- Haemoglobin < 11 g/dL (women); < 12.5 g/dL (men)
- BMI < 19 kg/m² and ≥ 30 kg/m²
- Intentional and unintentional weight loss > 5% in the previous 6 months
- Smoker
- Major medical or surgical event requiring hospitalization within the previous 3 months
- Presence of disease or drug(s) influencing digestion and absorption of nutrients or bowel habits
- Intake of medications known to affect glucose tolerance, e.g., steroids, protease inhibitors or antipsychotics (stable doses of e.g., oral contraceptives, thyroxin, vitamins and mineral supplements or drugs to treat hypertension or osteoporosis are acceptable)
- Chronic intake of substances affecting blood coagulation (e.g. acetylic acid, anticoagulants, diuretics, thiazides), which in the investigator’s opinion would impact volunteer safety
- Hereditary problems of galactose or fructose intolerance, lactase deficiency or glucose-galactose malabsorption
- Suspicion of drug abuse
- Abuse of alcoholic drinks, defined as an average daily intake of more than one litre of beer per day or equivalent amount of alcohol in other beverages
- Pregnant or breast feeding women
- Known or suspected allergy to any component of the investigational product(s)
- Known HIV-infection
- Known acute or chronic hepatitis B and C infection
- Blood donation within 4 weeks prior to visit 1 or during the study
- Volunteer unable to co-operate adequately
- Participation in a clinical trial with an investigational product within one month before start of study

Contacts/Locations

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References

Citations:

Links:

Study Data/Documents: