Trial Description

Title

Dietary intervention trial: single blinded placebo-controlled, randomized study to assess anti-diabetic effects of daily bitter gourd consumption among pre-diabetics in Moshi, Tanzania

Trial Acronym

MOCHI

URL of the trial

[---]*

Brief Summary in Lay Language

This study examines anti-diabetic effects of a daily bitter gourd consumption of 2.5 g among pre-diabetic people. Pre-diabetes is definded according to the American Diabetes Association. A person with a fasting plasma glucose level between 100 and below 126 mg/dl (5.6 – 6.9 mmol/l) is considered as pre-diabetic. Over a period of two months one group will receive bitter gourd sachets and one group placebo sachets. Then, a four week wash-out period, where no sachets are taken, is conducted. After that the group which received bitter gourd sachets will now get the placebo sachets and vice versa. Before and after each intervention phase with the sachets, different parameters in regard to blood sugar and blood lipids as well as body weight will be assessed. The study is going to take place in Moshi, Tanzania.

Brief Summary in Scientific Language

The planned dietary intervention study aims at assessing anti-diabetic effects of daily bitter gourd drink consumption of 2.5 g powder over the course of eight weeks among pre-diabetic persons. It is a single blinde, placebo-controlled, randomized, cross-over designed dietary intervention study. During the trial, data will be collected in regards to fasting plasma glucose levels, HbA1c, fructosamine, insulin, and lipids, anthropometrics, and blood pressure as well as socio-economic and medical history information, dietary intake, and physical activity,. The study will be conducted at the Kilimanjaro Clinical Research Centre, Moshi Tanzania.

Organizational Data

- DRKS-ID: **DRKS00005131**
- Date of Registration in DRKS: **2013/07/24**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **Approved**

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Ethics Approval/Approval of the Ethics Committee: **Approved**

- (leading) Ethics Committee Nr.: **[---]* , National Institute for Medical Research (NIMR), NIMR/HQ/r.8a/Vol.IX/1551**

Secondary IDs

Health condition or Problem studied

- Free text: **Pre-diabetes**

Interventions/Observational Groups

- Arm 1: **Bitter gourd sachets:**
  Bitter gourd powder (g): 2.5
  Cucumber powder (g):0.75
  Alpha-cyclodextrin* (g): 0.75
  Beta-cyclodextrin (mg): 75
  Steviol glycoside (mg): 15
  Total (g)4.090
  ***containing 2% (v/w) of lemon peel oil**
  Participants are requested to consume one sachet per day after the main meal,
- Arm 2: **Placebo sachet:**
  Cucumber powder (g): 3.25
  Alpha-cyclodextrin* (g): 0.75
  Beta-cyclodextrin (mg): 75
  Steviol glycoside (mg): 15
  Total (g): 4.090
  ***containing 2% (v/w) of lemon peel oil**
  Participants are requested to consume one sachet per day after the main meal, dissolved in 150 ml water. Sachets are going to be consumed over the course

Characteristics

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

Primary Outcome

Fasting plasma glucose: measured each at baseline and after each intervention of eight weeks (end assessment) as well as during the weekly check-ups.

Secondary Outcome

HbA1c, insulin, triglycerides, high-density lipoprotein, cholesterol:measured each at baseline and after each intervention of eight weeks (end assessment)
Body weight, waist circumference, blood pressure: measured each at baseline and after each intervention of eight weeks (end assessment) as well as during the weekly check-ups.

Countries of recruitment

- TZ **Tanzania, United Republic of**

Locations of Recruitment

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2013/07/28**
- Target Sample Size: **90**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **30 Years**
- Maximum Age: **60 Years**

Additional Inclusion Criteria

- BMI > 27 - < 35 kg/m²
- WC > 80 cm (women) > 94 cm (men)
- Being pre-diabetic according to:
- Fasting plasmae glucose (FPG) ≥ 100 – 125 mg/dl (≥ 5.6 – 6.9 mmol/l) on two screening days or FPG ≥ 100 – 125 mg/dl and HbA1c ≥ 5.7% < 6.5% on one screening day

Exclusion criteria

- Having diagnosed disease
- Having G6PD deficiency
- Taking any kind of medication regularly
- High blood pressure (>140/>90)
- Low blood pressure (<90/<60)
- Being mentally ill
- Pregnancy or planned pregnancy
- Breast-feeding
- Heavy alcohol consumption

Addresses

- **Primary Sponsor**

Bundesministerium für wirtschaftliche Zusammenarbeit und Entwicklung (BMZ)
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10963 Berlin
Germany

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- **Contact for Scientific Queries**

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■ **Collaborator, Other Address**

AVRDC - The World Vegetable Center;

KCMC - Kilimanjaro Christian Medical Centre

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Sources of Monetary or Material Support

■ **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

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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.*