**Trial Description**

**Title**

The Karlsruhe Metabolomics Project

**Trial Acronym**

KarMeN

**URL of the trial**

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**Brief Summary in Lay Language**

KarMeN, the „Karlsruhe Metabolomics and Nutrition“ is a project that investigates lifestyle factors such as nutrition and physical activity in relation to health. In this context metabolites as intermediate catabolic products play a major role. The metabolome is defined as the sum of all metabolites in an organisms at a given time point and may enable us to predict the health status. During 3 days healthy women and men above 18 years of age undergo clinical and other examinations. Body composition is determined and nutritional as well as physical activity questionnaires are applied. Metabolites are measured in blood and urine to identify associations with clinical examinations.

**Brief Summary in Scientific Language**

Metabolomics has become an important approach in nutrition and food research. It allows to analyse a wide range of small molecules present in a biological system. Major determinants of the human metabolome are not well defined, including the impact of acute and long-term food consumption, and of the level of physical activity and fitness. Therefore, the primary objective of this study is to assess the human metabolome in the Karlsruhe Metabolomics and Nutrition (KarMeN) cohort and its major life-style-related determinants. Metabolites are analysed in plasma and urine using a multi-method platform approach including NMR, GC-MS and LC-MS techniques. A well-characterised healthy cohort undergoes detailed examinations considering a strict schedule to guarantee standardized procedures. Clinical examinations (e.g. medical history, ECG, pulmonary function, DEXA, blood pressure, energy expenditure) as well as data on nutrient intake and physical activity are combined with the plasma and urine metabolome being evaluated by multivariate biostatistic methods.

**Organizational Data**
Arm 1: Healthy volunteers are examined by means of anthropometric, physiological and clinical methods. They answer questionnaires on nutrition and physical activity. Blood and urine is analysed by metabolomic techniques.

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

Human metabolome in fasting plasma (single morning blood sample) and 24h urine (previous day) (analysis by NMR, GCxGC-MS, LC-MS/MS)
Secondary Outcome

- nutrient intake (24h-recall questionnaire), physical activity (accelerometer, questionnaire), aerobic exercise capacity (cycle ergometry), anthropometry/body composition (DEXA), blood pressure (RR).
  - One-time examinations under standardised conditions and adherence to a strict schedule on the day before, during and after blood sampling.

Countries of recruitment

- DE Germany

Locations of Recruitment

- other Max Rubner-Institut, Karlsruhe

Recruitment

- Planned/Actual: Actual
- (Anticipated or Actual) Date of First Enrollment: 2012/05/02
- Target Sample Size: 300
- Monocenter/Multicenter trial: Monocenter trial
- National/International: National

Inclusion Criteria

- Gender: Both, male and female
- Minimum Age: 18 Years
- Maximum Age: 80 Years

Additional Inclusion Criteria

- healthy men and women;
- 18 - 80 years of age;
- non-smokers;
- participants who are able to conduct all tests;
- participants who gave written and informed consent.

Exclusion criteria

- smoker;
- volunteers with regular drug use;
- pregnant or breast feeding women;
- volunteers with diseases of the cardiovascular system, lungs, GI-trakt,
metabolism, skin, viscera, nervous system, and infectious or immunological
diseases in therapeutic need;
allergy against PABA (p-Aminobenzoesäure);
Intolerance against FINALGON;
volunteers with tumours;
volunteers with acute or chronic infectious diseases;
volunteers with drug or alcohol abuse;
volunteers who may not adhere to the study protocol;
volunteers that gave no written consent;
institutionalised patients in mental hospitals.

Addresses

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Sources of Monetary or Material Support

- Institutional budget, no external funding (budget of sponsor/PI)
  
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  E-mail: [---]*  
  URL: [---]*

Status

- Recruitment Status: Recruiting complete, follow-up complete
- Study Closing (LPLV): 2013/08/08

Trial Publications, Results and other documents

- Paper The Karlsruhe Metabolomics and Nutrition (KarMeN) Study: Protocol and Methods of a Cross-Sectional Study to Characterize

* 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.