

The Karlsruhe Metabolomics and Nutrition (KarMeN) Study: Protocol and Methods of a Cross-Sectional Study to Characterize the Metabolome of Healthy Men and Women*

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The human metabolome is influenced by various intrinsic and extrinsic factors. A precondition to identify such biomarkers is the comprehensive understanding of the composition and variability of the metabolome of healthy humans. Sample handling aspects have an important impact on the composition of the metabolome; therefore, it is crucial for any metabolomics study to standardize protocols on sample collection, pre-analytical sample handling, storage, and analytics to keep the non-biological variability as low as possible.

The main objective of the KarMeN study is to analyze the human metabolome in blood and urine by targeted and untargeted metabolite profiling (gas chromatography-mass spectrometry [GC-MS], GC×GC-MS, liquid chromatography-mass spectrometry [LC-MS/MS], and ¹H nuclear magnetic resonance [NMR] spectroscopy) and to determine the impact of sex, age, body composition, diet, and physical activity on metabolite profiles of healthy women and men. Here, we report the outline of the study protocol with special regard to all aspects that should be considered in studies applying metabolomics.

The project was funded in 2011 and enrollment was carried out between March 2012 and July 2013. A total of 301 volunteers were eligible to participate in the study. Metabolite profiling of plasma and urine samples has been completed and data analysis is currently underway. Metabolite analyses related to age, sex, resting energy expenditure, TMAO and diet will be presented at this conference.

We established the KarMeN study applying a broad set of clinical and physiological examinations with a high degree of standardization. Our experimental approach of combining scheduled timing of examinations and sampling with the multiplatform approach (GC×GC-MS, GC-MS, LC-MS/MS, and ¹H NMR spectroscopy) will enable us to differentiate between current and long-term effects of diet and physical activity on metabolite profiles, while enabling us at the same time to consider confounders such as age and sex in the KarMeN study.

Trial Registration: German Clinical Trials Register DRKS00004890; https://drks-neu.uniklinik-freiburg.de/drks_web/navigate.do?navigationId=trial.HTML&TRIAL_ID=DRKS00004890 (Archived by WebCite at <http://www.webcitation.org/6iyM8dMtx>)

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