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Determining the effects of vegan and omnivorous diets on the effects of exercise and the intestinal bacteria population in ultra-marathoners

Submission date 27/10/2020	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 08/12/2020	**Overall study status** Stopped	
Last Edited 18/07/2023	**Condition category** Other	

Plain English summary of protocol

Background and study aims
The gut microbiome is the totality of microorganisms, bacteria, viruses, protozoa, and fungi, and their collective genetic material present in the gastrointestinal tract.
Vegan diets have been widely adopted in the athletic population in recent years. However, the influence of vegan diets on exercise performance and energy processing (metabolism) is still controversial.
The study aims to determine gut microbiome adaptation to extreme endurance exercise according to vegan or omnivore diet consumed in ultra-marathoners. We also seek to evaluate long-term vegan and omnivore diets' effects on exercise capacity, oxidant/antioxidant capacity, muscle fatigue, and assess energy availability

Who can participate?
Ultra-marathoners with age between 18 to 49 years who are competing in the Sri-Chinmoy ultra-marathon race

What does the study involve?
Our study will run for one year. During this period, research data will be collected from the participants in four steps (three visits to the research laboratory and the race day) throughout the study. Study participants will be asked to visit the study laboratory for three times (first and second visits before the race and the third visit 24 hours after the race).

What are the possible benefits and risks of participating?
Participants will receive reliable information about their nutrition and performance status from health professionals.
There are no additional risks.

Where is the study run from?
1. University Hospital of Zurich (Switzerland)
2. Sri-Chinmoy race (St. Jakob sports complex) (Switzerland)

When is the study starting and how long is it expected to run for?
January 2020 to September 2023 (updated 22/07/2022, previously: September 2022; updated 13/04/2021, previously: May 2021)

Who is funding the study?
University Hospital of Zurich (Switzerland)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2013-KAEK-64

Study information

Scientific Title
Vegan vs. omnivore diets paradox: Determining the effects of dietary pattern on exercise-induced symptoms and a whole-metagenomic approach towards defining metabolic networks during the race in ultra-marathoners

Study objectives
1. According to gut metagenomics, vegan ultra-marathoners have higher alpha and beta diversity than omnivorous ultra-marathoners
2. Vegan ultra-marathoners have lower energy availability, macro- and micronutrient intakes than omnivore ultra-marathoners
2. Ultra-marathoners following a long-term vegan diet have a higher antioxidant capacity, lower oxidant capacity, and muscle fatigue than omnivorous ultra-marathoners
3. There is no difference between vegan and omnivorous ultra-endurance athletes in terms of gut microbiome adaptation to ultra-marathon races

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/06/2020, Istanbul Medeniyet University Göztepe Training and Research Hospital Clinical Research Ethics Committee (Doktor Erkin Street, Kadıköy / Istanbul, Turkey; +90216570 9190; etik@sbgoztepehastanesi.gov.tr), ref: 2020/0396

Study design
Before and after study design

Primary study design
Interventional

Secondary study design
Before and after study design

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied
Ultra-marathoners adhering to a vegan or omnivorous diet at least 6 months

Interventions
Participants will be classified as either vegan (no type of animal product consumption - dietary adherence <6 months) or omnivorous (consumption of any animal products - dietary adherence <6 months) based on self-reporting of diet consumed.

Twenty four participants will be assigned to the study, including twelve vegan and twelve omnivorous ultra-marathoners competing in the Sri-Chinmoy ultra marathon race. Research data will be collected at the University of Zurich Research Laboratory between June 2021 and August 2021, and on the Sri-Chinmoy ultra-marathon race day in July 2021. Research data will be collected from the participants at four steps (three visits to the research laboratory and the race day) throughout the study. At the first visit, fecal samples, and anthropometric measurements will be collected. Body composition will be measured using DXA. Participants will be informed about keeping detailed food and liquid records and will be asked to record their diet data during the study period. Additionally, they will be asked to wear accelerometers during this period. At second visit, maximum oxygen consumption will be measured on a treadmill. At the race day, blood samples will be collected immediately before, and 0. min, two hours, and 24 hours before the race. The blood and fecal samples will be stored at -80 C until analysis. Plasma malondialdehyde, reactive oxygen metabolites (d-ROMs), total antioxidant capacity, and HSP70, and serum Orosomucoid 1 will be analyzed in blood samples. Fecal samples will be analyzed with shotgun metagenomic analysis and interpreted using the bioinformatics pipeline (HumanN2). Statistical tests will be analyzed using SPSS version 23.0 (IBM, Armonk, NY) and R Software (Dusseldorf, Germany). Laboratory analyses will be covered by the Institute of Primary Care, University Hospital Zurich.

Individual results of the VO2max values, nutritional assessment according to food and fluid records, energy availability, body mineral density, and microbiota structure will be discussed in detail with the participants. Further, they will receive individual consultations on obtaining adequate energy and nutrient intake. As a result of this study, participants will receive reliable information about their nutrition and performance status from health professionals.
The increase of heart rate during the incremental running test will be continuously monitored in order to prevent an adverse reaction, and only healthy participants with no history of cardiovascular disease will be invited to participate in the study. The Physical Activity Readiness Questionnaire (PAR-Q) will be applied to assess current cardiovascular health. Participants answering no to all questions will be considered as eligible for physical activity. The standard emergency equipment will be available in the research laboratory. Blood samples will be collected by a healthcare professional while the participants are positioned in a semi-reclined position to avoid risks associated with blood collection. Lactate measurements will be performed using sterile lancets to prevent risk of exposure to bloodborne pathogens.

Intervention Type
Other

Primary outcome measure
Intestinal microbial adaptation according to applied diet evaluated by analysing faecal samples taken seven days before and seven days after the race using shotgun metagenomic analysis

Secondary outcome measures
Oxidative stress and muscle fatigue-related biomarkers measured using blood samples immediately before, at the end of 0 h, 2 h and 24 h of the race

Overall study start date
01/01/2020

Completion date
30/09/2023

Reason abandoned (if study stopped)
Objectives no longer viable

Eligibility

Key inclusion criteria
1. Ultra-marathoners with age between 18 to 49 years
2. Competing in the Sri-Chinmoy ultra-marathon race
3. No use of probiotics and antibiotics in the preceding 3 months
4. No history of acute or chronic illnesses

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
49 Years

Sex
Both

Target number of participants
24

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment

01/01/2021

Date of final enrolment
21/07/2023

Locations

Countries of recruitment
Switzerland

Study participating centre
University Hospital Zurich
Institute of Primary Care
Zurich
Switzerland
8091

Study participating centre
Sri-Chinmoy race (St. Jakob sports complex)
Brüglingerstrasse 21
Basel
Switzerland
4052

Sponsor information

Organisation
University Hospital of Zurich

Sponsor details
Institute of Primary Care
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Switzerland
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Sponsor type
Hospital/treatment centre

Website
http://www.en.usz.ch/Pages/default.aspx

ROR
https://ror.org/01462r250

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Universitätsspital Zürich

Alternative Name(s)
University Hospital Zurich, USZ

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Germany

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/01/2024

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	23/09/2021	24/09/2021	Yes	No