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The effects of 10-day complete fasting on human health and metabolism

Submission date
17/05/2022

Recruitment status
No longer recruiting

Registration date
24/05/2022

Overall study status
Completed

Last Edited
10/06/2025

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Fasting is beneficial to many aspects of human health and shows great potential for the treatment of chronic metabolic diseases. The aim of this study is to investigate the safety and the effects on metabolism and health of prolonged water-only fasting. The study's findings should provide evidence to design a new fasting therapeutic strategy for clinical practice.

Who can participate?
Healthy men aged 25 to 55 years with body mass index (BMI) from 19 to 32 kg/m²

What does the study involve?
Participants are recruited and must pass a health examination. The whole experiment lasted 22 days including a 3-day baseline (BL), 10-day complete fasting (CF), 4-day calorie restriction diet (CR) and 5-day full recovery diet (FR) in a controlled building. During the CF period, participants are only permitted to drink water when they want and perform normal activities in the lab building. In the CR phase, the participants are given gradually increased amounts of food to protect their digestive system after CF. During the FR phase, the participants are allowed to return to their normal eating habits. Bodyweight, resting blood pressure and pulse, blood glucose and ketones (β-hydroxybutyrate) are monitored every day in CF and CR. Blood, urine and feces will be collected for routine tests and to measure metabolism, hormones and cytokines at six timepoints including one time before CF, three times during CF, one time during CR and one time in FR. Questionnaires about psychological mood are taken at the same times. Resting metabolic rate will be measured at five timepoints (before, twp times during and two times after).

What are the possible benefits and risks of participating?
There is no economic benefit, but fasting may help to improve health, and the results will help to design new fasting modes even for spaceflight. The main risk is low blood glucose, which will be monitored every day and at any time needed. The whole study will be conducted under medical supervision.

Where is the study run from?
Space Science and Technology Institute (China)

When is the study starting and how long is it expected to run for?
January 2018 to June 2018

Who is funding the study?
1. State Key Laboratory of Space Medicine Fundamentals and Application and the China Astronaut Research and Training Center (China)
2. Advanced Space Medico-Engineering Research Project of China (China)
3. Space Medical Experiment Project of China Manned Space Program (China)

Who is the main contact?
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Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
SMFA17A02

Study information

Scientific Title
The effects of 10-day complete fasting hypometabolism on human health and homeostasis

Study objectives
Based on Chinese traditional health methods, in this human experiment fasting was used to change metabolism in order to explain the change pattern and switch time window of energy substrate utilization (glucose-fat-protein), the metabolic change of tissue organ functions such as liver, fat, and intestinal microecology, and the alteration of regulating hormones to appetite, blood sugar, lipid metabolism and others, and to explore the feasibility of using fasting to induce and maintain a hypometabolic state during spaceflight.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/05/2018, Biomedical Research Ethics Committee Involving People of the Space Science and Technology Institute (4 Shamiao Road, Longgang District, Shenzhen, Guangdong, China; +86 (0)13688832866; 312506571@qq.com), ref: not applicable

Study design
Interventional case series

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Effects of complete fasting on human health and metabolism

Interventions
10-day water-only fasting in a controlled building including 3-day baseline (BL), 10-day complete fasting (CF), 4-day calorie restriction (CR) and 5-day full recovery (FR). Health status is assessed by monitoring pulse, blood pressure, body weight (BW), blood glucose and ketone, nutritional indices, body composition and biochemistry indexes at different times. Blood, urine and feces are collected to further analyze hormones, cytokines, and intestinal microecology.

Intervention Type
Behavioural

Primary outcome(s)
1. Body weight is measured by an electric scale every day throughout the study
2. Blood pressure is measured by an electronic blood pressure monitor every day throughout the study
3. Blood glucose and ketone determined by test strip every day or by a biochemistry method at six timepoints (3 days before fasting, the 3rd day, 6th day and 9th day during fasting, 3 days and 8 days after resuming diet) in hospital
4. Urine acid is measured by biochemistry method in hospital at six timepoints (3 days before fasting, the 3rd day, 6th day and 9th day during fasting, 3 days and 8 days after resuming diet)
5. Body compostion measured by dual-energy X-ray absorptiometry (DEXA) or sfb7 at three timepoints (3 days before fasting, 6th day during fasting 10 days after resuming diet)
6. Blood routine examination in hospital at six timepoints (3 days before fasting, the 3rd day, 6th day and 9th day during fasting, 3 days and 8 days after resuming diet)

7. Psychological mood is measured using the Profle of Mood State (POMS), Visual Analogue Scales (VAS), Self-rating Anxiety Scale (SAS), Self-rating Depression Scale (SDS), Work Ability Index (WAI), Stanford Sleepiness Scale (SSS) at six timepoints (3 days before fasting, the 3rd day, 6th day and 9th day during fasting, 3 days and 8 days after resuming diet

Key secondary outcome(s))
1. Hormones and cytokines measured by ELISA or biochemistry at six timepoints (3 days before fasting, the 3rd day, 6th day and 9th day during fasting, 3 days and 8 days after resuming diet)
2. Resting metabolic rate is measured by indirect calorimetry at five timepoints (2 days before fasting, 3rd and 9th day during fasting, 3 days and 7-8 days after resuming diet)

Completion date
08/06/2018

Eligibility

Key inclusion criteria
1. Healthy male
2. 25-55 years old
3. BMI 20-32 kg/m²

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
Male

Total final enrolment
13

Key exclusion criteria
1. Malignant tumor
2. Serious cardiovascular diseases (congenital heart disease, myocardial infarction, coronary heart disease, angina pectoris, etc)
3. Infectious disease
4. Mental disorders
5. Anemia
6. Hypotension
7. Diabetes mellitus
8. History of gastrointestinal ulcer
9. Other after medical examination

Date of first enrolment
03/05/2018

Date of final enrolment
10/05/2018

Locations

Countries of recruitment
China

Study participating centre
Space Science and Technology Institute
4 Shamiao Road
Longgang District
Shenzhen
China
518117

Sponsor information

Organisation
State Key Laboratory of Space Medicine Fundamentals and Application and the China Astronaut Research and Training Center

Funder(s)

Funder type
Research organisation

Funder Name
State Key Laboratory of Space Medicine Fundamentals and Application, China Astronaut Research and Training Center (SMFA17A02, SMFA18B02, SMFA18B06, SMFA19C01, SMFA19C03)

Alternative Name(s)

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
China

Funder Name
Science, Technology and Innovation Commission of Shenzhen Municipality 2020 Basic Research Project (JCYJ20200109110630285).

Alternative Name(s)
Shenzhen Science and Technology Innovation Commission, Shenzhen Science and Technology Innovation Committee,

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
China

Funder Name
Advanced Space Medico-Engineering Research Project of China (18035020103)

Funder Name
Space Medical Experiment Project of China Manned Space Program (HYZHXM01002)

Results and Publications

Individual participant data (IPD) sharing plan
Data requests should be sent to Zhongquan Dai (daizhq77@163.com). The researchers will provide all the data after they have been published in a journal. Any researcher interested in prolonged fasting can request the data, but not the private data of volunteers by email, if they demonstrate their previous research.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		03/01/2021	19/05/2022	Yes	No
Results article		19/05/2021	19/05/2022	Yes	No
Results article		18/09/2022	06/10/2022	Yes	No
Results article		26/12/2024	10/06/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes