

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

Submission date 17/05/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 24/05/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 10/06/2025	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> 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, two 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?

Zhongquan Dai
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Contact information

Type(s)

Principal Investigator

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary 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 participant information sheet

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 measure

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 composition 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 Profile 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)

Secondary outcome measures

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)

Overall study start date

01/01/2018

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

Age group

Adult

Sex

Male

Target number of participants

14

Total final enrolment

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**

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Sponsor information**Organisation**

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

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Sponsor type

Research organisation

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

Publication and dissemination plan

The researchers plan to publish in an international peer-reviewed journal.

Intention to publish date

23/12/2022

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