

Effects of fasting on your body may differ according to your genes

Submission date 10/06/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 16/06/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 16/06/2021	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Haptoglobin is a protein produced by the liver that the body uses to clear free hemoglobin (found outside of red blood cells) from circulation.

Serum haptoglobin (Hp) is an acute-phase protein that is crucial for the neutralization of oxidative damage and the elimination of free hemoglobin. The current study aimed to examine the impact of observing four consecutive weeks, dawn to sunset intermittent fasting (IF) among people with overweight and obesity.

Who can participate?

Any metabolically healthy male or female adult subject (>18 years) with overweight/obesity (BMI>25 kg/m²), willing to fast for consecutive four weeks from dawn to sunset, and willing to participate and sign the informed consent.

What does the study involve?

The study involves observing the body weight changes, blood inflammatory, and biochemical metabolic measurement before and after the commencement of four-week consecutive dawn to sunset intermittent fasting.

What are the possible benefits and risks of participating?

The study will benefit the participant in controlling his body weight and body composition, inflammatory and metabolic markers related to chronic diseases over two months (before and after the commencement of IF). Many beneficial metabolic and inflammatory improvements are expected to gain by the participants according to the available literature on IF. No harm is expected after observing IF for one month, as IF is considered safe for metabolically healthy overweight and obese people with no predetermined diseases.

The participant may experience slight discomfort due to blood sampling.

Where is the study run from?

University Hospital of Sharjah, Sharjah University (UAE)

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

December 2015 to October 2016

Who is funding the study?
Sharjah University (UAE)

Who is the main contact?
Dr. Moez AllIslam Faris, mfaris@sharjah.ac.ae

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
Nil known

Study information

Scientific Title
Impact of four consecutive weeks, dawn to sunset intermittent fasting on CD163 and haptoglobin inflammatory markers among haptoglobin polymorphisms in overweight/obese subjects

Acronym
RAMFAST

Study objectives

Impact of four consecutive weeks, dawn to sunset intermittent fasting on CD163, and haptoglobin inflammatory markers in overweight/obese subjects will differ according to the haptoglobin polymorphisms

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 15/05/2016, Research Ethics Committee, University of Sharjah (Sharjah 27272, UAE; +971 65057304; rec@sharjah.ac.ae), ref: REC/15/12/16/002

Study design

Observational prospective cohort

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Prevention

Participant information sheet

<https://drive.google.com/file/d/198rkJ888dieP1OTvhWpaCAnb5nhcLvFH/view>

Health condition(s) or problem(s) studied

Prevention of inflammatory and metabolic complications in metabolically healthy overweight and obese subjects

Interventions

Volunteers willing to participate and practice intermittent fasting for four consecutive weeks from dawn to sunset were recruited. Body weight, height, and body measurements, blood samples and food intakes were taken one week before the commencement of intermittent fasting, and after completing the four consecutive weeks of intermittent fasting. Total duration of the fasting was consecutive 29-30 days. No follow-up after completing the four weeks intermittent fasting.

Intervention Type

Behavioural

Primary outcome measure

Measured using blood test:

1. Haptoglobin gene polymorphism genotype (fixed outcome), serum CD136, and serum haptoglobin were determined at baseline
2. Serum CD136, and serum haptoglobin levels were measured after four-week consecutive intermittent fasting

Secondary outcome measures

Measured at baseline, and after four weeks intermittent fasting:

1. Body weight (kg), BMI (kg/m²)
2. Inflammatory (IL-6, TNF-alpha, IL-10) and metabolic markers (lipid profile, glucose homeostasis) measured using blood test

Overall study start date

01/12/2015

Completion date

01/10/2016

Eligibility

Key inclusion criteria

1. Metabolically healthy male or female adult subject (>18 years)
2. Overweight/obesity (BMI>25 kg/m²)
3. Willing to fast for consecutive four weeks from dawn to sunset, and willing to participate and sign the informed consent

Participant type(s)

Healthy volunteer

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

50

Total final enrolment

65

Key exclusion criteria

1. History of metabolic syndrome, diabetes, or cardiovascular disease
2. Taking regular medications or supplements
3. Following a weight-reducing diet
4. History of bariatric surgery within the last 6-9 months before commencing intermittent fasting
5. Pregnant or peri-menopausal woman

Date of first enrolment

01/05/2016

Date of final enrolment

15/06/2016

Locations

Countries of recruitment

United Arab Emirates

Study participating centre

University of Sharjah

Research Institute for Medical and Health Sciences

University City Of Sharjah

Sharjah

United Arab Emirates

27272

Sponsor information

Organisation

University of Sharjah

Sponsor details

University city of Sharjah

Sharjah

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smirza@sharjah.ac.ae

Sponsor type

University/education

Website

<https://www.sharjah.ac.ae/en/Pages/default.aspx>

ROR

<https://ror.org/00engpz63>

Funder(s)

Funder type

Not defined

Funder Name

University of Sharjah

Alternative Name(s)

, jāmiat aš-šāriqah, The University of Sharjah, UOS

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

United Arab Emirates

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

01/07/2021

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

MoezAllIslam Faris, mfaris@sharjah.ac.ae

Type of data: Raw data, master Excel sheet

When the data will become available and for how long? Will be available once the request received, and for one-week

By what access criteria data will be shared including with whom? By Drop Box repository special link can only be opened by those who have the link

For what types of analyses? Only for secondary and meta-analysis, not for original work re-analysis.

Whether consent from participants was obtained: Yes, obtained

Comments on data anonymization: All data are anonymized, no names or any personal identification information is used.

Any ethical or legal restrictions, any other comments: Data were obtained following the Helsinki Declaration for research ethics_

IPD sharing plan summary

Available on request