

Effects of Ramadan fasting on cholesterol-metabolizing protein PCSK9 in people with obesity

Submission date 18/06/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 28/09/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 18/06/2021	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

Diet changes are important to help patients to lower their high blood cholesterol. One of the factors that affect blood cholesterol is a blood protein called PCSK9, which helps in regulating blood cholesterol, so some medications try to affect this protein in an attempt to lower blood cholesterol. Abstinence from food and drink for a specific time period is called intermittent fasting. This type of fasting has been shown to have beneficial effects on human health and disease. Thus, the aim of this study is to find out whether practising fasting during the holy month of Ramadan can affect the PCSK9 protein in adult healthy Muslims.

Who can participate?

Healthy adults (aged over 18 years) with overweight/obesity (BMI >25 kg/m²), willing to fast for 4 consecutive weeks from dawn to sunset

What does the study involve?

The study involves observing the changes in body weight and blood test results before and after 4 weeks of dawn to sunset intermittent fasting.

What are the possible benefits and risks of participating?

The study may benefit help participants to control their body weight, body composition and inflammatory and metabolic markers related to chronic diseases. No harm is expected from intermittent fasting for 1 month, as intermittent fasting 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 (United Arab Emirates)

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

November 2015 to October 2016

Who is funding the study?
The University of Sharjah (United Arab Emirates)

Who is the main contact?
Dr Moez Al-Islam Faris
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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

Nil known

Study information

Scientific Title

Association of Ramadan intermittent fasting with changes in circulating proprotein convertase subtilisin/kexin type 9 (PCSK9) in metabolically healthy obese subjects

Acronym

RAMFAST

Study objectives

Four consecutive weeks, dawn to sunset intermittent fasting will lead to changes in circulating PCSK9 cholesterol metabolism marker in people with obesity

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 29/11/2015, Research Ethics Committee, The University of Sharjah (Sharjah 27272, UAE; +971 (0)65057304; rec@sharjah.ac.ae), ref: ERC 29/11/15/49

Study design

Observational prospective cohort study

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/1ff8dAUXffnPkJiUbuP5ZuyAzZTfzMkHX/view?usp=sharing>

Health condition(s) or problem(s) studied

Prevention of elevated cholesterol by lowering circulating PCSK9 in metabolically healthy people with obesity

Interventions

Volunteers willing to participate and practice intermittent fasting for 4 consecutive weeks from dawn to sunset are recruited. Body weight, height, and body measurements, blood samples and food intake are measured 1 week before the commencement of intermittent fasting, and after

completing the 4 consecutive weeks of intermittent fasting. The total duration of the fasting is 29-30 consecutive days. There is no follow-up after completing the 4 weeks of intermittent fasting.

Intervention Type

Behavioural

Primary outcome measure

Blood PCSK9 levels measured using enzyme-linked immunosorbent assay (ELISA) at baseline (pre-fasting) and after 4-week consecutive dawn to sunset intermittent fasting

Secondary outcome measures

Measured using Analyzer machine at baseline, and after 4 weeks intermittent fasting:

1. Body weight (kg), BMI, fat mass, fat-free mass, and visceral fat surface area
2. Total cholesterol, triglycerides, HDL, LDL, fasting blood glucose

Overall study start date

29/11/2015

Completion date

01/10/2016

Eligibility

Key inclusion criteria

1. Metabolically healthy male or female adult subject (>18 years)
2. Overweight/obesity (body mass index (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

60

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

University City of Sharjah

Sharjah

United Arab Emirates

27272

Sponsor information

Organisation

University of Sharjah

Sponsor details

Sharjah University City

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+971 (0)65157514

mfaris@sharjah.ac.ae

Sponsor type

University/education

Website

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

ROR

Funder(s)

Funder type

University/education

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/will be available upon request from Dr Moez Al-Islam 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 is received for 1 week

By what access criteria data will be shared including with whom: by DropBox repository special link that 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 are 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