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

Submission date
18/06/2021

Recruitment status
No longer recruiting

Registration date
28/09/2021

Overall study status
Completed

Last Edited
18/06/2021

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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/m^2), 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?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
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

Study type(s)
Prevention

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

Key secondary outcome(s))

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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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

ROR
https://ror.org/00engpz63

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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes