

Investigating the effects of low saturated fat ketogenic diet on lipaemia in lean and obese healthy participants in Kuwait

Submission date 03/12/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 16/04/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 28/03/2025	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

This study aims to explore the effects of different diets on health markers such as cholesterol levels and blood pressure. Researchers hope to understand how diet can influence these markers in both lean and obese individuals.

Who can participate?

Participants can be men or women aged between 18 and 60 years. They should either be lean (with a BMI between 18.5 and 24.9 kg/m²) or obese (with a BMI above 29.9 kg/m²). Participants must be willing to follow a specific diet for the duration of the study and be able to provide informed consent. They should not be taking lipid-lowering or blood pressure medications.

What does the study involve?

Participants will follow a specific diet plan provided by the researchers. They will have regular check-ups to monitor their health markers, such as cholesterol levels and blood pressure. The study will involve dietary assessments and possibly blood tests to track changes over time.

What are the possible benefits and risks of participating?

Participants may benefit from gaining insights into their health and how their diet affects it. However, there are risks such as potential side effects from dietary changes, and the inconvenience of regular check-ups and tests.

Where is the study run from?

University of Aberdeen (UK)

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

September 2024 to December 2025

Who is funding the study?

Dasman Diabetes Institute (Kuwait)

Who is the main contact?
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Contact information

Type(s)

Scientific, Principal Investigator

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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

Investigating the effects of low saturated fat ketogenic diet on lipaemia in lean and obese healthy participants in Kuwait

Acronym

IESFKD

Study objectives

To determine the effect of low- and high- saturated fat ketogenic diets on lipid profile and microbiota in lean and obese healthy participants in Kuwait

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 30/09/2024, Dr. Fatmah Abdul Rahman AlNajjar (Kuwait Public Health Ministry, Asimah, -, Kuwait; 1810005; appsupport@moh.gov.kw), ref: 1601

Study design

Interventional randomized parallel trial

Primary study design

Interventional

Secondary study design

Randomised parallel trial

Study setting(s)

Hospital

Study type(s)

Efficacy

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

The effect of low or high saturated fat ketogenic diet on lipidemia

Interventions

A randomized parallel clinical trial will be conducted for 4 weeks to assess the impact of high and low saturated fat KD (SFKD) on lipid profile and microbiota of healthy lean and obese participants.

- The high SFKD will consist of approximately 70-75% fat (40% saturated fat), 20-25% protein

(1.7 grams/kg), and 5-10% carbohydrate (less than 100 grams/day).

- The low SFKD will consist of approximately 70-75% fat (10% saturated fat), 20-25% protein (1.7 grams/kg), and 5-10% carbohydrate (less than 100 grams/day).

Participants are randomized using an online tool.

Intervention Type

Other

Primary outcome measure

Lipid profile from baseline (Week 1) and (week 4) through blood samples

Secondary outcome measures

1. Triglyceride, HDL, glucose, and insulin sensitivity will be measured by blood sample at baseline (week 1) and at (week 4)
2. Gut microbiome activity and composition will be through stool sample collection from week 1 and week 4
3. Body composition measured using DEXA at week 1 and week 4. For blood pressure it will be measured at week 1 and week 4

Overall study start date

30/09/2024

Completion date

01/12/2025

Eligibility

Key inclusion criteria

1. Age between 18 and 60 years
2. Male or female participants
3. Lean group: BMI between 18.5 and 24.9 kg/m²
4. Obese group: BMI above 29.9 kg/m²
5. Willingness to adhere to the assigned diet for the duration of the study
6. Ability to provide informed consent
7. No use of lipid-lowering medication
8. No use of blood pressure medication

Participant type(s)

All

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

Both

Target number of participants

96

Key exclusion criteria

1. For lean participants, elevated lipid profile defined by total cholesterol above 5.2 mmol/L and LDL above 3.5 mmol/L with triglyceride HDL ratio between 4.0 to 6.0. For obese participants, total cholesterol above 6 mmol/L and LDL above 5 mmol/L
2. Cardiovascular diseases
3. Eating disorder
4. Diagnosed with hypertension (above 140/90 mmHg) and taking blood pressure medications such as ACE inhibitors, calcium channel blockers, or diuretics
5. Being pregnant
6. Food allergies
7. Inflammatory bowel disease
8. Irritable bowel syndrome
9. Non-alcoholic fatty liver

Date of first enrolment

01/12/2024

Date of final enrolment

01/12/2024

Locations**Countries of recruitment**

Kuwait

Study participating centre**Dasman Diabetes Institute**

Gulf Road intersecting Jassim Al Bahar St.
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Asimah
Kuwait
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Sponsor information**Organisation**

University of Aberdeen

Sponsor details

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Sponsor type

University/education

Website

<http://www.abdn.ac.uk/>

ROR

<https://ror.org/016476m91>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Dasman Diabetes Institute

Alternative Name(s)

Dasman Institute, DDI

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

Kuwait

Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed journal

Intention to publish date

18/06/2026

Individual participant data (IPD) sharing plan

The datasets generated during and analysed during the current study will be available upon request from f.thies@abdn.ac.uk

IPD sharing plan summary

Available on request