ISRCTN30944171 https://doi.org/10.1186/ISRCTN30944171

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

Registration date
16/04/2025

Overall study status
Completed

Last Edited
28/03/2025

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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?
habooots@gmail.com
f.thies@abdn.ac.uk

Contact information

Type(s)
Scientific, Principal investigator

Contact name
Prof Frank Thies

ORCID ID
https://orcid.org/0000-0002-9275-9713

Contact details
School of Medicine, medical Sciences and Nutrition, Rowett Institute, Foresterhill
Aberdeen
United Kingdom
AB25 2ZD
+44 (0)1224 437954
f.thies@abdn.ac.uk

Type(s)
Public, Scientific

Contact name
Mrs Hebah Ben Salamah

ORCID ID
https://orcid.org/0009-0002-0918-5024

Contact details
Qadiseya block 9 st 92 house 16
Asimah
Kuwait
-
+965 65555551
r01hb23@abdn.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Efficacy

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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

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.
Sharq, Block 3, P.O. Box 1180 Dasman
Asimah
Kuwait
1180

Sponsor information

Organisation
University of Aberdeen

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

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