

Effects of a short term Palaeolithic diet on fasting insulin, leptin and weight

Submission date 27/07/2016	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 28/07/2016	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 13/12/2019	Condition category Nutritional, Metabolic, Endocrine	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Background and study aims

Obesity and diabetes are on the rise, and have become a major health concern worldwide. There is a strong link between obesity and type two diabetes (a long term health condition where a person has difficulty controlling their blood sugar levels as they do not produce enough insulin to function properly (insulin deficiency), or that the body's cells don't react to insulin as they should do (insulin resistance)). There is some uncertainty and controversy with regard to the best diet for health and for the prevention of obesity and diabetes. The Paleolithic diet, sometimes called the "stone age diet", is the diet that man ate for the first 95% of his existence. It involves eating the foods available during human evolution (root vegetables, leafy vegetables, fruits, nuts, eggs, lean meat, fish and shellfish), and equally importantly it involves cutting out grains, refined vegetable seed oils, refined sugar, dairy products, soya products and pulses and legumes (i.e. lentils, beans and peanuts). Studies have shown that this type of diet could have an effect on blood sugar levels and the levels of a hormone called leptin. Many "healthy" people have some degree of insulin resistance; the aim of this study was to see whether the insulin sensitivity of healthy volunteers might improve with a Palaeolithic diet, even if they were previously classified as having normal insulin sensitivity.

Who can participate?

Healthy adults.

What does the study involve?

Participants are encouraged to consume a Paleolithic diet for four weeks. This involves cutting out grains, refined vegetable seed oils, refined sugar, dairy products, soya products and pulses and legumes (i.e. lentils, beans and peanuts), and replacing them with fruit, vegetables, root vegetables, fish, lean meat, eggs and nuts. Participants can eat as much as they like of "allowed" foods, however must not have more than 30g of nuts or one potato per day. For non-Caucasian participants, if they feel they are unable to stick to the diet for four weeks, they are able to do so for two weeks instead. At the start of the study and then after the diet ends (two or four weeks), participants are weighed and provide blood samples so that their blood sugar, fat levels and leptin (hormone) levels can be measured. Before the blood tests, participants must not eat or drink anything except water for 12 hours.

What are the possible benefits and risks of participating?

Participants may benefit from weight loss in those who are overweight and improvements in insulin sensitivity in those with insulin resistance. There are no notable risks for participants, however some may feel discomfort or experience bruising from blood tests.

Where is the study run from?

The study takes place in participants homes and blood testing takes place at Blue Horizon Blood tests London (UK) and in home visits from the company Metropolis Healthcare Ltd (India)

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

April 2015 to July 2016

Who is funding the study?

Investigator initiated and funded (UK)

Who is the main contact?

Dr Madhvi Chanrai

Contact information

Type(s)

Public

Contact name

Dr Madhvi Chanrai

Contact details

Adamson Road
London
United Kingdom
NW3 3HR

Additional identifiers

Protocol serial number

1

Study information

Scientific Title

Effects of a short term Palaeolithic diet on fasting leptin, insulin and weight in 41 healthy participants - an uncontrolled observational study

Study objectives

The aim of this study is to look at the effects on insulin, leptin and weight after following a Palaeolithic diet for two weeks or four weeks.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Single-arm non-randomised study

Primary study design

Interventional

Study type(s)

Other

Health condition(s) or problem(s) studied

Insulin resistance

Interventions

All participants are encouraged to consume a Paleolithic diet for four weeks. This involves exclusion of grains, refined vegetable seed oils, refined sugar, dairy products, soya products and legumes; and replacing these foods with fruit, vegetables, root vegetables, fish, lean meat, eggs and nuts. All other foods can be consumed in unlimited quantities, but with no more than 30g nuts and 1 potato per day.

If non-Caucasian participants felt they could not follow the diet for four weeks, they are given the option of following it for two weeks. Caucasians and participants with pre-diabetes are excluded from the two week study.

Intervention Type

Other

Primary outcome(s)

1. Weight is measured in kg using a scale at home at baseline and 4 weeks (2 weeks for those following the 2 week diet)
2. Fasting insulin is measured using analysis of blood samples at baseline and 4 weeks (2 weeks for those following the 2 week diet)
3. Fasting leptin is measured using analysis of blood samples at baseline and 4 weeks (2 weeks for those following the 2 week diet)

Key secondary outcome(s)

1. Fasting lipids is measured using analysis of blood samples at baseline and 4 weeks (2 weeks for those following the 2 week diet)
2. Fasting glucose is measured using analysis of blood samples at baseline and 4 weeks (2 weeks for those following the 2 week diet)

Completion date

06/07/2016

Eligibility**Key inclusion criteria**

1. Male or female
2. Age range 18 to 80
3. Healthy

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

Serious medical conditions.

Date of first enrolment

01/04/2015

Date of final enrolment

28/06/2016

Locations

Countries of recruitment

United Kingdom

England

India

Study participating centre

Blue Horizon Blood tests London

76 Wimpole Street

London

United Kingdom

W1G 9RT

Study participating centre

Metropolis Healthcare Ltd
-
Mumbai and Kolkata
India
-

Sponsor information

Organisation
Dr Madhvi Chanrai

Funder(s)

Funder type
Not defined

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

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