ISRCTN47734717 https://doi.org/10.1186/ISRCTN47734717

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

Submission date
27/07/2016

Recruitment status
No longer recruiting

Registration date
28/07/2016

Overall study status
Completed

Last Edited
13/12/2019

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
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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Non randomised study

Study setting(s)
Home

Study type(s)
Other

Participant information sheet
http://thedoctorsdigest.com/participant-information-sheet-for-a-two-week-or-four-week-palaeolithic-diet-study/

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 an 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 measure
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)

Secondary outcome measures
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)

Overall study start date
27/04/2015

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
41

Key exclusion criteria
Serious medical conditions.

Date of first enrolment
01/04/2015

Date of final enrolment
28/06/2016

Locations

Countries of recruitment

England

India

United Kingdom

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

Sponsor details
Adamson Road
London
United Kingdom
NW3 3HR

Sponsor type
Other

Funder(s)

Funder type
Not defined

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
30/06/2017

Individual participant data (IPD) sharing plan

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