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Hormonal profiles modification, lower hunger scores, better anthropometric outcomes and reduced risk factors of the metabolic syndrome following a weight loss diet with carbohydrates eaten only at dinner

Submission date
23/11/2009

Recruitment status
No longer recruiting

Registration date
03/12/2009

Overall study status
Completed

Last Edited
06/02/2014

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomised clinical trial examining leptin, ghrelin and adiponectin diurnal profiles modifications, hunger and satiety scores, anthropometric, biochemical and inflammation parameters following a weight loss diet with carbohydrates eaten only at dinner.

Study objectives
Obesity is often accompanied by uncontrolled hunger, insulin resistance and by the metabolic syndrome. The adipose tissue, "the energy storage site of the body", is also an endocrine organ that synthesizes and secretes a variety of adipocytokines. This includes hormones regulating hunger and satiety and associated with the development of insulin resistance, the metabolic syndrome and inflammation.

Hypotheses:
1. A weight loss diet with carbohydrates eaten only at dinner (the experimental diet) will lead to modifications of the typical diurnal pattern of leptin, and to higher relative concentrations throughout the day, helping experimental diet participants to experience satiety during the day and to better adhere to their diets.
2. Ghrelin's diurnal pattern will be inverted too, leading to the appearance of hunger sensations later in the day.
3. The experimental diet will increase adiponectin concentrations throughout the day, leading to improved insulin resistance, diminished symptoms of the metabolic syndrome and better inflammation profiles.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the Regional Committee for Human Experimentation, Kaplan Hospital, Israel in accordance with the Helsinki declaration of 1975 (revised in 1983). (ref: 024/2006)

Study design
Single centre randomised controlled parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Obesity; metabolic syndrome

Interventions
100 officers enrolled to a randomised single centre controlled interventional diet study. 78 Individuals met study criteria and were randomly allocated to the experimental/control groups.

A standard low calorie diet (20% protein, 30-35% fat, 45-50% carbohydrates, 1300-1500 kcal) providing carbohydrates only at dinner (Experimental diet) or a standard low calorie diet (20% protein, 30-35% fat, 45-50% carbohydrates, 1300-1500 kcal), providing carbohydrates throughout the day (control diet) was consumed for 6 months
Blood samples were taken and the participants filled out hunger-satiety scales every 4 hours between 8:00-20:00 at day 0, 7, 90 and 180.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Leptin, ghrelin (total) and adiponectin (High Molecular Weight) (Linco research sandwich ELISA kits)
2. Insulin (Abbot Microparticle Enzyme Immunoassay test kits)
3. Hunger-Satiety Score (H-SSc) a scale of descriptions from hunger to satiety (1= starving, 10= devastatingly full).
4. Glucose (Olympus enzymatic UV test kits)
5. Insulin resistance (Homeostasis Model Assesment)
6. Cholesterol, HDL-cholesterol, LDL-cholesterol and triglycerides (Olympus enzymatic colour test kits)
7. C-reactive protein (CRP) (Olympus Immunoturbidimetric test kits)
8. TNF-α (Human Serum [HS]) and IL-6 (HS) (R&D systems sandwich ELISA kits)

Secondary outcome measures
1. Weight, abdominal circumference, and percentage of body fat were measured regularly and on day o, 7, 90,180.
2. "Urge to eat" and "preoccupation with thoughts about food".

Overall study start date
22/05/2006

Completion date
09/09/2007

Eligibility

Key inclusion criteria

1. Police officers from the Israeli Police Force (men and women)
2. Age 25-55
3. BMI >30

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
80

Key exclusion criteria
1. Cardiovascular diseases
2. Hypertension
3. Diabetes mellitus or other primary diseases
4. Followed any type of diet regime within a year prior to the study
5. Pregnancy

Date of first enrolment
22/05/2006

Date of final enrolment
09/09/2007

Locations

Countries of recruitment
Israel

Study participating centre
P.O Box 12
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Sponsor information

Organisation
The Hebrew University of Jerusalem (Israel)

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The Robert H. Smith Faculty of Agriculture,
Food and Environment,
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Sponsor type
University/education

ROR
https://ror.org/03qxff017

Funder(s)

Funder type
Other

Funder Name
Meuhedet Medical Services (Israel)

Funder Name
Kaplan Medical Center, Rehovot (Israel)

Funder Name
Israeli Police Force (Israel)

Funder Name
Israel Diabetes Association (Israel)

Funder Name
Israel Lung and Tuberculosis Association (Israel)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2013		Yes	No