Effects of an intervention with a Paleolithic diet in subjects with the metabolic syndrome (MetS). A pilot-study.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22601

Source
NTR

Health condition

Metabolic Syndome, Metabool syndroom, Cardiovascular risk, Cardiovasculair risico

Sponsors and support

Primary sponsor: Louis Bolk Institute, Driebergen
WUR, Wageningen
UMCG, Groningen
University of Gerona, Spain
Source(s) of monetary or material Support: Innovatienetwerk, Universiteit van Gerona, Fonds van het Hart, Louis Bolk Instituut

Intervention

Outcome measures

Primary outcome

Parameters of the MetS:

1. Oral glucose tolerance;

2. Fasting insulin, glucose, systolic /diastolic blood pressure, serum total-, LDL- and HDL-cholesterol and triglycerides.

Secondary outcome

1. Intestinal permeability;

2. HOMA;

3. Body weight and waist circumference;

4. Inflammation parameters;

5. Salitivary cortisol.

Safety parameters:

1. Adverse events;

2. Hematology;

3. Liver and kidney function.

Study description

Background summary

N/A

Study objective

Working hypothesis is that a Palaeolithic diet can improve the parameters of the MetS: glucose tolerance, fasting insulin, fasting glucose, serum total-, LDL- and HDL-cholesterol and triglycerides, waist circumference and blood pressure through metabolic alterations that are independent of weight loss.

To study whether there are changes in the different parameters of the MetS as a result of a Palaeolithic diet compared to an isocaloric reference diet, to use this knowledge in the design of future trials.
1. To get insight which specific parameters show changes and their effect size;

2. To study other variables, which are assumed to be positively influenced by the Palaeolithic diet;

3. To study feasibility of a Palaeolithic diet.

Study design

1. Visit 1 (week -2): Informed consent, run-in on usual diet, blood sampling;

2. Visit 2 (week -0.5): Non-invasive measurements;

3. Visit 3 (week 0): Baseline blood sampling, randomization, start dietary intervention;

4. Visit 4 (week 2): Non-invasive measurements;

5. Visit 5 (week 2 + 1 day): Blood sampling, end of study.

Intervention

Intervention: A Paleolithic diet (2 weeks);

Control: An isocaloric diet consistent with ‘Guidelines for a healthy diet 2006’ of the Health Council of the Netherlands (2 weeks).

Contacts

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Eligibility criteria

Inclusion criteria

1. Written informed consent;

2. Age ≥ 18 and < 60 years;

3. At least 2 of the following:

A. Central obesity (waist circumference ≥ 102 cm (male) and ≥ 88 cm (female);

B. Elevated triglycerides: TG ≥ 1.7 mmol /l;

C. Reduced HDL cholesterol: HDL-C < 1.0 mmol /l (male) and <1.3 mmol /l (female);

D. Raised blood pressure ≥ 130 /85 mmHg or medication for hypertension;

E. Elevated fasting plasma glucose ≥ 5.6 mmol /l;

F. Willingness not to consume alcohol during the intervention.

Exclusion criteria

1. Diabetes mellitus type 2, cardiovascular diseases, stroke, cancer and psychological disorders;

2. Systolic blood pressure > 180 mmHg;

3. Smoking (within a month prior to the study);

4. 10 years mortality risk caused by cardiovascular disease > 10 % according to NHG-standard M84 Cardiovascular Risk Management (November 2006);

5. Concomitant pharmacological treatment with hypoglycemic agents, insulin, warfarin or oral steroids;

6. Participation in an other clinical trial at the same time or within the previous month prior to enrolment into this study;

7. Pregnancy or lactation;

8. Recent blood donation (within the last 2 months);

9. Severe internal or systemic disease (e.g. cardiac, hepatic, renal diseases);

10. Non –omnivore (e.g. vegan, vegetarian);

11. Unwillingness to eat fish.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2011
Enrollment:	36
Type:	Actual

Ethics review

Positive opinion

Date:	25-07-2011
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 36767
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2860
NTR-old	NTR3002
CCMO	NL31294.081.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON36767

Study results

Summary results
Favourable effects of consuming a Palaeolithic-type diet on characteristics of the metabolic syndrome: a randomized controlled pilot-study.
Inge Boers, Frits AJ Muskiet, Evert Berkelaar, Erik Schut, Ria Penders, Karine Hoenderdos, Harry J Wichers and Miek C Jong
Lipids in Health and Disease: http://www.lipidworld.com/content/13/1/160