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

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Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22601

Bron
NTR

Aandoening

Metabolic Syndome, Metabool syndroom, Cardiovascular risk, Cardiovasculair risico

Ondersteuning

Primaire sponsor: Louis Bolk Institute, Driebergen
WUR, Wageningen
UMCG, Groningen
University of Gerona, Spain
Overige ondersteuning: Innovatienetwerk, Universiteit van Gerona, Fonds van het Hart, Louis Bolk Instituut

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Parameters of the MetS:
1. Oral glucose tolerance;
2. Fasting insulin, glucose, systolic /diastolic blood pressure, serum total-, LDL- and HDL-cholesterol and triglycerides.

Toelichting onderzoek

Achtergrond van het onderzoek

N/A

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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).

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-03-2011
Aantal proefpersonen:	36
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	25-07-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 36767
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
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