Effects of a Paleolithic diet in subjects with markers of the metabolic syndrome. A pilot-study.

Published: 11-04-2011
Last updated: 15-05-2024

We propose a 2-week randomized controlled, single-blinded pilot study to compare the health effects of a Paleolithic diet and an isocaloric reference diet (based on the *Guidelines for a healthy diet 2006*) on markers of the MetS which are risk...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON36767

Source
ToetsingOnline

Brief title
Health effects of a Paleolithic diet

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Glucose metabolism disorders (incl diabetes mellitus)
- Vascular hypertensive disorders

Synonym
high risk for cardovascular diseases and diabetes mellitus, Metabolic Syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Louis Bolk Instituut

Source(s) of monetary or material Support: Innovatie netwerk;Universiteit van Gerona;Spanje;Fonds van het Hart

Intervention

Keyword: Dietary management, Glucose tolerance, Insulin resistance, Metabolic syndrome

Outcome measures

Primary outcome

Parameters of the MetS:

•Oral glucose tolerance

•Fasting insulin, glucose, systolic /diastolic blood pressure, serum total-,

LDL- and HDL-cholesterol and triglycerides .

Secondary outcome

•Intestinal permeability

•HOMA

•Body weight and waist circumference

•Inflammation parameters

•Salitivary cortisol

Study description

Background summary

The metabolic syndrome is a clustering of symptoms that reflect overnutrition, sedentary lifestyles, and resultant excess adiposity. There are at least 5 definitions of the metabolic syndrome (Cornier et al., 2008). As a common denominator, they all include (abdominal) obesity, insulin resistance/compromised glucose homeostasis, dyslipidemia, and elevated blood pressure and these are associated with diseases and conditions such as the prothrombotic state, proinflammatory state, non-alcoholic fatty liver disease, reproductive disorders and most prominently diabetes mellitus type 2 and cardiovascular disease. The metabolic syndrome has become one of the major

public health concerns worldwide, not only affecting the industrialized world, but also the developing nations which experience a rapid transition of nutrition. The prevalence of the metabolic syndrome is increasing to epidemic proportions, affecting up to 12-40% of subjects, depending on the definition, sex, race, country and others (Lorenzo et al., 2007; Cameron et al., 2007; Deepa et al, 2007; Csaszar et al, 2006). Since the prevalence of the metabolic syndrome world wide is increasing towards epidemic proportions and individuals with the metabolic syndrome are at high risk to progress into type 2 diabetes mellitus (Grundy 2006; Ford et al., 2008) or cardiovascular disorders (CVD) (Gami et al., 2007), prevention is warranted. The prevalence of MetS in the Netherlands is about 15.5% (Donk van den et al. 2009), even in a young adult population of the age of 36 years in the Netherlands was 18.3% in men and 3.2% in women according to the Amsterdam Growth and Health Longitudinal Study (Ferreira et al. 2005)From an evolutionary approach it has been postulated that foods that were regularly eaten by hunter-gatherers during human evolution, in particular during the Paleolithic (the old stone age, 2.5 - 0.01 million years BP), may be optimal for prevention and treatment of metabolic disorders such as obesity, type 2 diabetes mellitus, cardiovascular disease and insulin resistance (Cordain et al., 2005; Eaton et. al, 1997,2000; Jansson, 1990; Mann, 2004, O*Keefe et al., 2004, Sebastian et al., 2002, 2006). A Paleolithic diet of these days is a modern dietary regimen based on lean meat, fish, shellfish, fruits, vegetables, roots, eggs and nuts. The Paleolithic diet contains no grains, dairy products, added salt or refined fat and sugar (Cordain et al. 2000). Recent studies in nonobese healthy volunteers have shown that a Paleolithic diet effectively lowers blood pressure, body weight, waist circumference, body mass index (BMI) (Osterdahl et al. 2008), but also serum lipids (LDL-cholesterol and triglycerides) and plasma insulin versus time Area Under the Curve, during an Oral Glucose Tolerance Test (OGTT) (Frasetto et al. 2009). These favorable effects in healthy volunteers were observed within a relatively short period of dietary intervention i.e. less than 2-3 weeks. The major limitation of the studies by Osterdahl (2008) and Frasetto (2009) were the lack of a control group. In a study by Lindeberg et al (2007) the effect of a Paleolithic diet was compared to a Mediterranean diet in subjects with ischaemic heart disease. A larger improvement of glucose tolerance was observed after a Paleolithic diet. In line with these findings, a Paleolithic diet significantly improved glycemic control compared to a conventional diabetes diet in patients with type 2 diabetes (Jonsson et al. 2009). Although dietary management and lifestyle modifications are considered to be the cornerstone in the treatment and prevention of metabolic disorders, specific guidelines for treatment of the metabolic syndrome have not yet been established . A moderate weight loss (5-10%) has shown to be beneficial in subjects with the metabolic syndrome (Ilanne-Parikka et al., 2008). However, more research is needed to identify which metabolic markers/pathways can be positively influenced by different types of diet, independent of weight loss, and which nutrient components in a diet may improve the metabolic and

physiological status of subjects with the metabolic syndrome. Based on the previously published favorable effects in subjects with type 2 Diabetes and ischaemic heart disease, the present study has been proposed to investigate whether a Paleolithic diet may be effective in subjects with the metabolic syndrome.

Study objective

We propose a 2-week randomized controlled, single-blinded pilot study to compare the health effects of a Paleolithic diet and an isocaloric reference diet (based on the *Guidelines for a healthy diet 2006*) on markers of the MetS which are risk factors for the initiation and further progression into DM2 and CVD.

The aim of the present pilot is 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. It has been hypothesized that a change in the diet to one that resembles that of hunter-gatherers would be beneficial to health. Recent studies have shown that consumption of a Paleolithic type diet, high in lean meats, fruits, vegetables and nuts, rapidly leads to metabolic and physiologic improvement in subjects with DM2 and ischemic heart disease.

-The main goal is to get insight which specific parameters show changes and their effect size, to use this knowledge in the design of probable future trials. Until now there is no research about the possible health effects of Palaeolithic nutrition in subjects with the MetS. In former research about the effects of a Palaeolithic diet, discussion was raised whether this positive health effects could be caused by less energy intake or weight loss. In our present pilot study we will try to keep energy intake and weight stable in both intervention groups.

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.

-Next to this we aim to study some other outcome variables, which are assumed to be positively influenced by the Palaeolithic diet: inflammation parameters, intestinal permeability, HOMA and the diurnal cortisol slope in subjects with the MetS through metabolic alterations that are independent of weight loss. Possible alterations in these outcome parameters may give new insights in the pathophysiological mechanisms underling the MetS and CVD.

-Another goal of the study is to obtain more information on feasibility and how to design and develop an innovative dietary prevention program on the basis of a Palaeolithic diet. Since specific guidelines for the treatment of the MetS are lacking, a dietary Palaeolithic program of which the effects are

scientifically evaluated, may contribute to the prevention of the MetS and further development into CVD and DM2

Study design

A randomized, controlled, single-blinded pilot study.

Intervention

A Paleolithic diet for 14 days compared to an isocaloric diet consistent with *Guidelines for a healthy diet 2006* of the Health Council of the Netherlands.

Study burden and risks

To our knowledge, no study has been performed up till now in which the effects of a Paleolithic diet are investigated in subjects with the metabolic syndrome. Innovative elements in the proposed study are reflected in the defined primary and secondary outcome criteria. Besides the well-known risk factors as fasting glucose, insulin, serum lipids and glucose intolerance, other outcome parameters will be measured such as endothelial dysfunction, intestinal permeability and fatty acid composition of erythrocytes. Possible positive alterations in these outcome parameters may have great benefits for the participating subjects. Since specific guidelines for the treatment of the metabolic syndrome are lacking, a dietary Paleolithic program of which the effects are scientifically evaluated, may contribute to the prevention of the metabolic syndrome and further development into type 2 diabetes mellitus and cardiovascular disease.

The study intervention is a diet intervention. There are no negative influences known or expected from either the paleolithic diet, as from the reference diet. According to protocol guidelines participants will access at 5 visits. Bloodsamples will be drawn (3 times) and 24 hr-urine will be collected (2 times), subjects will have short time fasting periodes (from 20.00 oclock in the evening) till examination/ measurements the next morning (5 times), and non-invasive measurements will be performed (2 times). Risks for participating subjects are expected to be low. All measurements will be performed in a 15 days period, so it will be a high intensive, but rather short ,low-risk burden on participating subjects.

Contacts

Public
Louis Bolk Instituut

Hoofdstraat 24
3972 LA Driebergen
NL
Scientific
Louis Bolk Instituut

Hoofdstraat 24
3972 LA Driebergen
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

-Written informed consent
-Age >= 18 and < 70 years
-At least 2 of the following:
-Central obesity (waist circumference >= 102 cm (male) and >= 88 cm (female)
-Elevated triglycerides: TG >= 1.7 mmol/L
-Reduced HDL cholesterol: HDL-C < 1.0 mmol/l (male) and <1.3 mmol/l (female)
-Raised blood pressure >= 130/85 mmHg or medication for hypertension
-Elevated fasting plasma glucose >= 5.6 mmol/L
•Willingness to not consume alcohol during the intervention

Exclusion criteria

-Diabetes mellitus type 2, cardiovascular diseases, stroke, cancer and psychological disorders
-Systolic bloodpressure > 180 mmHg
-Smoking (within a month prior to the study)
-10 years mortality risk caused by cardiovascular disease > 10 % according to NHG-standard M84 Cardiovascular Risk Management (November 2006)

-Concomitant pharmacological treatment with hypoglycaemic agents, insulin, warfarin or oral steroids
-Participation in an other clinical trial at the same time or within the previous month prior to enrolment into this study
-Pregnancy or lactation
-Recent blood donation (within the last 2 months)
-Severe internal or systemic disease (e.g. cardiac, hepatic, renal diseases).
-Non -omnivore (e.g. vegan, vegetarian)
-Unwillingness to eat fish

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-10-2011
Enrollment:	36
Type:	Actual

Ethics review

Approved WMO Date:	11-04-2011
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)
Approved WMO Date:	18-10-2011

Application type:	Amendment
Review commission:	METC Wageningen Universiteit (Wageningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 22601
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL31294.081.10
OMON	NL-OMON22601

Study results

Date completed:	01-07-2012
Actual enrolment:	34