Cross-over randomized placebo-controlled pilot study to determine the effect in healthy elderly volunteers of the anti-ageing supplement *Promanna** on a number of biomarkers associated with DNA-damage and oxidative stress (PromAge)

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Determining the effect of short term ProManna intake on physiological parameters, notably biomarkers of oxidative stress. This pilot study serves to investigate whether ProManna intake leads to any changes in baseline levels for oxidative stress...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON40413

Source
ToetsingOnline

Brief title
Effect of an anti-ageing supplement on oxidative stress

Condition

- Other condition

Synonym
NA (this is about healthy ageing)

Health condition

Niet van toepassing, het gaat om gezonde vrijwilligers.

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Tender subsidie SNN (Samenwerkingsverband Noord Nederland)

Intervention

Keyword: DNA-damage, healthy aging, Nutritional supplement, oxidative stress

Outcome measures

Primary outcome

The main study parameters are:

• Changes in baseline levels for oxidative stress markers following 2 weeks intake of ProManna versus placebo

• Comparison of oxidative stress responses following a hyperoxia or glucose challenge in subjects taking ProManna or placebo.

Secondary outcome

Results from questionnaires and biomarker studies will be used to design a long-term intervention study that will investigate the effect of ProManna on physical and mental parameters.

Study description

Background summary

Ageing is characterized by a progressive decline in the efficiency of

physiological function and by the increased susceptibility to disease and death. Most ageing-associated diseases develop silently for many years before symptoms appear, leading to irreversible pathological conditions. Examples of these diseases are Alzheimer*s, Parkinson*s, osteoporosis, diabetes, cardiovascular disease and also cancer. Typically, patients are treated when most of the damage has already occurred, and existing drugs can rarely cure these diseases, but merely slow down further progression of the disease. Therefore, preventive measures that may delay the onset of these diseases can hold the best promise for healthy ageing.
Currently, one of the most plausible and acceptable explanations for the mechanistic basis of aging is the *free radical theory of aging*. This theory postulates that aging and its related diseases are the consequence of free radical-induced damage to cellular macromolecules and the inability to counterbalance these changes by endogenous anti-oxidant defences. ProManna is a novel and safe food supplement that aims to decrease free radical-induced damage, thereby contributing to healthy ageing.

Study objective

Determining the effect of short term ProManna intake on physiological parameters, notably biomarkers of oxidative stress. This pilot study serves to investigate whether ProManna intake leads to any changes in baseline levels for oxidative stress markers. In addition, biomarker responses following oxidative stress challenge tests will be assessed in subjects taking ProManna versus placebo supplements. Results from this study will be used to set up a long term clinical study that will investigate the effect of ProManna supplementation on physical and mental parameters of elderly.

Study design

a randomized, placebo-controlled cross-over study.

Intervention

Use of ProManna for two weeks.

Study burden and risks

This is a non-therapeutic study with healthy volunteers. The investigational product is a safe food supplement and administration is oral and burden-free. There is a small chance that some participants may develop mild diarrhoea during the first days after ProManna intake but earlier studies showed that this is only transient. Participants will be required to provide small volumes of blood and urine for baseline testing and to complete questionnaires. Participants attend baseline measurements before the study and before the start of the second study period after cross over. The baseline consists of a short

visit to the research lab, getting information about the study and giving a blood sample. Besides that, there will be a total of 4 test days of one morning per participant, and prior to test day 1 and 3, participants are asked to collect 24h urine samples. Tests consist of hyperoxia and oral glucose tolerance testing followed by blood sampling. During blood-sampling there is a small chance of bleeding at the puncture site, fainting or light skin infection. The physical examination is relatively simple, carried out by trained research nurses and is not very stressful for participants. Mentioned risks are rare if performed by qualified personnel at UMCG

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following

criteria:
1. Healthy volunteer aged >= 60 to <= 70
2. Not involved in intensive sportive activities more than twice a week (e.g. playing football, tennis, running, cycling-racing, swimming)
3. Stable weight and no intention to lose weight until completion of the study (three times a day: a normal eating pattern).
4. Two weeks before the start and during the study no use of over the counter medication, prescribed medication, herbal medication or dietary supplements which in the investigator's opinion could affect study results, or which could be affected by the study product (i.e. absorption of oral medication will be influenced by D-Mannitol). Exception for sporadic use of paracetamol and/or treating an AE.
5. Able and motivated to comply with protocol requirements like for instance take the investigational product the way it is prescribed and to do the tests.
6. Voluntary signed written informed consent form (ICF) before the start of the pilot.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
1. BMI < 25 or > 30 kg/m2
2. Not being able to fast overnight (8 hours)
3. Diabetes mellitus
4. Gastrointestinal disorders
5. Undergone digestive tract surgery (except appendectomy)
6. Clinically significant inflammatory disease (possibly interfering with measurement of parameters in this study)
7. Weed smoking
8. Donation of blood within the last 3 months prior to admission to the clinic
9. Participation to another clinical study within 90 days before enrolment
10. Clinically relevant abnormalities in clinical chemistry or positive HIV, HbsAg and/or HepC at screening
11. Positive drug screen or alcohol breath test at D-1

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-09-2014
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	30-09-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL47431.042.14