The effect of isoflavone supplement intake on gene-expression in postmenopausal women

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Primary objective: to determine the effect of intake of one dose of isoflavones, as compared to placebo, for eight weeks on gene-expression in Peripheral Blood Mononuclear Cells (PBMCs) in post-menopausal, equol-producing women.Secondary Objectives...

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

Summary

ID

NL-OMON34551

Source
ToetsingOnline

Brief title
ISO study

Condition

- Other condition

Synonym
nvt

Health condition

geen specifieke aandoening, door het gebruik van micro-arrays

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: Voedsel en Warenauthoriteit

Intervention

Keyword: gene-expression, intervention, isoflavone, peripheral blood mononuclear cells

Outcome measures

Primary outcome

The main study parameter is gene-expression measured by micro-arrays.

Secondary outcome

Isoflavone levels in plasma and in spoturine

Study description

Background summary

Alleged benefits experienced by the consumption of soy in Asian countries have been attributed to the isoflavone content of soy products. Amongst other benefits, isoflavones are believed to relieve menopausal symptoms and are therefore often consumed in supplement form in Western countries. These supplements contain relatively high amounts of isoflavones, and the question is if these concentrations still exert beneficial effects or whether negative effects become dominant. At the moment, the European Food Safety Authority (EFSA) is also taking a better look at the potential health effects of isoflavones.

Study objective

Primary objective: to determine the effect of intake of one dose of isoflavones, as compared to placebo, for eight weeks on gene-expression in Peripheral Blood Mononuclear Cells (PBMCs) in post-menopausal, equol-producing women.
Secondary Objectives: to determine the association between isoflavone plasma levels and gene-expression in PBMCs;
to determine the variation of isoflavone plasma levels between subjects after intake of isoflavones for four and eight weeks;
to explore whether PBMC gene-expression markers identified after 8 weeks

isoflavone intervention are already present after 4 weeks intervention;
to explore whether the severity of previous menopausal complaints is related to the effect of isoflavones on PBMC gene-expression;
and
to explore the association between isoflavone levels in plasma and spot urine.

Study design

Double-blind placebo controlled crossover intervention study

Intervention

Two intervention periods of eight weeks with a isoflavone supplement or a placebo and a washout period of 8 weeks in between.

Study burden and risks

The subjects have to fill in a short screening questionnaire, a questionnaire regarding their menopausal complaints, and twice a food frequency questionnaire. The subjects have to visit the research centre 6 times, with their morning urine, to give a blood sample, to measure their arterial stiffness and to be weighed. In total the subjects spend, actively, around 9 hours in the study.
On the basis of the existing material there is no evidence that these supplements are unsafe. There are indications of concern in the scope of effects on hormone-sensitive breast cancer and for babies fed with soy infant formula, based on in vitro and animal studies and not supported by clinical and epidemiological studies. In the present study, however, persons with history of cancer are excluded.
At present, there is not enough human data to draw firm conclusions about the safety of isoflavones. Therefore the present study is important. Isoflavones can exert, after long-term usage of high doses, positive as well as negative effects. In the present study we will explore the effects of isoflavone intake on a broad scale with the use of micro-arrays. The supplements that will be used are commercially available and the dose is equal to the dose that producers subscribe. In literature we found 14 studies that use a dosage higher than 100 mg/day for a longer exposure time than in the present study. These studies did not report adverse effects
Venapunctures can occasionally cause a local hematoma or bruise and some participants may report pain or discomfort.

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

women
45-70 year
post-menopausal
equol-producing

Exclusion criteria

current use of contraceptives containing hormones
current use of hormone replacement therapy
current soy product use (more than once a week)
current isoflavone supplement use (more than once a week)
current use of medication containing sexhormones or sexhormone-triggering compounds
current use of anti-inflammatory drugs
use of antibiotics in the past 6 months
severe heart disease
thyroid disorders
complete ovarectomy

thyroidectomy
prior diagnosis of cancer in medical history
Alcohol and drug abuse
Current smoking habits
BMI >35 kg/m2
allergic to soy (products)

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-10-2010
Enrollment:	36
Type:	Actual

Ethics review

Approved WMO

Date:	20-08-2010
Application type:	First submission
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

No registrations found.

In other registers

Register	ID
CCMO	NL32375.081.10