Effects of two different isoflavone supplement preparations on gene-expression in postmenopausal women

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Primary Objective: • to study the effect of intake of two isoflavone preparations, as compared to placebo, for eight weeks on gene-expression in Peripheral Blood Mononuclear Cells (PBMCs) in post-menopausal women.Secondary Objectives: • to determine...

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

Summary

ID

NL-OMON35572

Source
ToetsingOnline

Brief title
ISO II study

Condition

- Other condition

Synonym
nvt

Health condition

geen specifieke aandoening door het gebruik van microarrays

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-expresion in PBMCs measured by micro-arrays

Secondary outcome

Isoflavone levels in plasma

Gene - expression measured by micro-arrays in adipose tissue

Isoflavone levels in adipose tissue.

Study description

Background summary

Alleged benefits experience 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 relief menopausal symptoms and are therefore often consumed in supplements form in Western countries. These supplements contain relatively high amounts of isoflavones and are on the market in different compositions. The question is whether supplements with different compositions exert similar effects or if the effects differ substantially.

Study objective

Primary Objective:
• to study the effect of intake of two isoflavone preparations, as compared to placebo, for eight weeks on gene-expression in Peripheral Blood Mononuclear Cells (PBMCs) in post-menopausal women.

Secondary Objectives:

• to determine the association between isoflavone plasma levels and gene-expression in PBMCs;
• to explore the difference between the two isoflavone preparations on gene-expression;
• to explore the difference between the two isoflavone preparations on status markers in plasma;
• to explore whether the severity of previous menopausal complaints is related to the effect of isoflavones on PBMC gene-expression;
• To explore the influence of isoflavones on whole genome gene expression in adipose tissue
• To compare isoflavone levels in plasma with the levels present in adipose tissue
• To determine the association between isoflavone levels in adipose tissue to gene expression in adipose tissue

Study design

Intervention study with two substudies; each substudy is a double blind placebo controlled crossover intervention study. The first substudy has two groups: *high daidzein* supplement versus placebo (n=18) and vice versa (n=18); the second substudy also has two groups *high genistein* versus placebo (n=18) and vice versa (n=18).

Intervention

Two intervention periods of eight weeks with an one of the two isoflavone supplements and a placebo for each subject 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, 4 times to give a blood samples and to be weighed. Twice of these 4 visits they can (voluntarily) undergo a adipose tissue biopsy. The other two times the participants visit to pick up new supplements and a diary. In total the subjects spend, actively, around 5.5 hours in the study excluding travelling time.
There are only very limited risks for the particpants during the intervention. The supplements that are used in the study are commercially available. The dose that will be used is similar to doses recommended by the supplement manufacturers on the packages, and has olso been used in other intervention studies. Venapunctures and adipose tissue biopsies can occasionally cause a local haematoma 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
50-70 year
postmenopausal

Exclusion criteria

- current use of contraceptives containing hormones
- current use of hormone replacement therapy
- regular soy product use (more than once a week)
- regular isoflavone supplement use (more than once a week)
- current use of medication containing sexhormones or sexhormone-triggering compounds

- current use of anti-inflammatory medicines
- use of antibiotics in the past 3 months
- severe heart disease
- diabetes
- thyroid disorders --> use of medicines for thyroid disorders
- removed thyroid gland
- complete ovarectomy
- prior diagnosis of cancer in medical history
- alcohol and drug abuse
- current smoker
- BMI >35 kg/m2
- allergy 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):	07-02-2012
Enrollment:	72
Type:	Actual

Ethics review

Approved WMO

Date:	21-11-2011
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	NL37475.081.11