# The estrogenic activity of phytoestrogens in soy meassured with the ER-CALUX assay.

Published: 11-08-2006 Last updated: 14-05-2024

To investigate the serum estrogenic activity of phyto-estrogens in healthy male volunteers, measured with the ER-CALUX assay after intake of soy nuts.

Ethical review	Approved WMO
Status	Pending
Health condition type	Endocrine disorders of gonadal function
Study type	Interventional

# Summary

### ID

NL-OMON29807

**Source** ToetsingOnline

**Brief title** The estrogenic activity of soy

### Condition

• Endocrine disorders of gonadal function

#### Synonym

transient endocrine disruption/ hormone dysregulation

#### **Research involving** Human

### **Sponsors and support**

Primary sponsor: Universitair Medisch Centrum Sint Radboud Source(s) of monetary or material Support: VIDI subsidie in het kader van de NWO vernieuwingsimpuls

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### Intervention

Keyword: estrogen activity, phyto-estrogens, soy

### **Outcome measures**

#### **Primary outcome**

The primary endpoint of the study is the total serum estrogenic activity

measured with the ER-CALUX assay and expressed in estradiol equivalents (EEQs).

#### Secondary outcome

Information will be collected about background variables and potential

confounders, such as age, BMI, and consumed foodstuffs and potential

gastro-intestinal problems during the study.

# **Study description**

### **Background summary**

Soybeans and soy-based foodstuffs such as tofu contain high concentrations of phyto-estrogens. Phyto-estrogens are structurally and functionally similar to endogenous estrogens, which is why they are able to bind with the estrogen receptor and exert agonistic or antagonistic effects. Previous studies showed that a soy-rich diet may lead to high serum concentrations of genistein and daidzein, the two main metabolites of phyto-estrogens. Whether this also results in altered estrogenic activity is yet unknown. In the present study, the effects of soy intake will be assessed using a new technique, the Estrogen-Responsive - CALUX assay (ER-CALUX), which measures the total estrogenic receptor activity in serum. With this assay, we attempt to elucidate the biological relevance of phyto-estrogens that are present in soy-based foodstuffs.

### **Study objective**

To investigate the serum estrogenic activity of phyto-estrogens in healthy male volunteers, measured with the ER-CALUX assay after intake of soy nuts.

### Study design

In this explorative study, serum estrogenic activity will be measured at variouspoints in time after intake of 50 grams of soy nuts by five of the six participants. The first blood sample will be collected just before the intervention, around 8:30 a.m. Subsequently, 4 blood samples will be taken at three-hour intervals. The final blood sample is taken around 8:30 a.m. the next morning. In order to get reference values, 6 blood samples are also drawn from one participant who did not eat soy products.

#### Intervention

The intervention studied is a single intake of 50 grams of soy nuts, which are available at a Herbalife reform shop and contain approximately 75 mgs of phyto-estrogens, which corresponds with a traditional soy-rich diet. Additionally, participants are not allowed to eat other soy-rich products in the three days before and during the study.

#### Study burden and risks

Participants are unlikely to consider the intervention of soy nut intake to be a burden. The burden consist mainly of the vena punction, which is repeated six times within a period of 24 hours. The vena punction is performed by an experienced research assistant and in close proximity of a medical doctor.

# 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**

- Healthy men

- Age 18 25
- BMI 18.5 25

### **Exclusion criteria**

- use of anti-coagulants

- diagnosis diabetes, thyroid disorder or other chronic illness that potentially involves a disturbed endocrine system

- use of hormonal medication
- chronic kidney or liver disorder
- use of antibiotics three months before the experiment
- use of meat or dairy substitutes at least two times a week for the last six months
- soy allergy
- smoking

# Study design

### Design

Primary purpose: Treatment	
Masking:	Open (masking not used)
Allocation:	Non-randomized controlled trial
Intervention model:	Other
Study type:	Interventional

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# Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	10-05-2006
Enrollment:	6
Туре:	Anticipated

# **Ethics review**

Approved WMO	
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

# **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 CCMO ID NL11432.091.06