ISRCTN98074661 https://doi.org/10.1186/ISRCTN98074661

# Effect of soy isoflavones and ascorbic acid supplementation on antioxidant activity in postmenopausal women

| | | |
|---|---|---|
| **Submission date**<br>04/01/2005 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>24/02/2005 | **Overall study status**<br>Completed | |
| **Last Edited**<br>19/09/2017 | **Condition category**<br>Signs and Symptoms | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Dr Andrea Hutchins

**Contact details**
Department of Nutrition
Arizona State University
7001 East Williams Field Road
Mesa
United States of America
85212
+1 480 727 1097
andrea.hutchins@asu.edu

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

N/A

# Study information

### Scientific Title
Effect of soy isoflavones and ascorbic acid supplementation on antioxidant activity in postmenopausal women: a randomised controlled trial

### Study objectives
This study investigated the extent to which vitamin C and isoflavones, as single or combined supplements to a habitual diet, provided antioxidant effects by reducing lipid oxidation in blood. Healthy, non-smoking, postmenopausal women were screened for regular soy consumption (one serving per day), vitamin C supplementation (60 mg/day), and postmenopausal status.

Utilising a randomised, double blind, crossover design, ten subjects were assigned to one of four dietary treatments. Subjects were instructed to continue their habitual physical activity and dietary habits during the 14-week experiment. The subjects completed consecutive two-day diet and activity logs immediately prior to each fasted blood draw. Diet and activity logs were analysed. Fasting blood was collected in vacuutainers, centrifuged, and plasma aliquots were frozen at -70°C for later analysis.

Plasma vitamin C concentration was determined using a 2,4-dinitrophenylhydrazine method by Omaye. Lipid peroxides were measured using the flurometric method. Total cholesterol was determined by a photometric assay; high-density lipoprotein (HDL) cholesterol by a homogenous enzyme immunoassay; and, triglycerides and low-density lipoprotein (LDL) cholesterol by a colorimetric assay (performed by Sonora Quest Laboratories, Phoenix, AZ).

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
The Human Subjects Committee of the Institutional Review Board of Arizona State University approved this study; all participants gave written informed consent before participating.

### Study design
Randomised, double blind, crossover designed study

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Not specified

### Study type(s)
Treatment

### Participant information sheet

### Health condition(s) or problem(s) studied
Antioxidant markers and risk factors for heart disease

### Interventions
Ten subjects were assigned to one of four dietary treatments:
1. Supplement of 5 mg isoflavones per kg/body weight (IF)
2. 500 mg vitamin C supplement (VC)
3. Supplement of 5 mg isoflavones per kg/body weight and 500 mg vitamin C supplement (IF-VC)
4. Placebo (C)

The two week treatment periods were separated by a two week washout period.

### Intervention Type
Supplement

### Phase
Not Specified

### Drug/device/biological/vaccine name(s)
Vitamin C and isoflavones

### Primary outcome measure
Lipid peroxides

### Secondary outcome measures
1. Vitamin C
2. Total cholesterol, including LDL, HDL and Triglycerides (TG)
3. Blood pressure

### Overall study start date
01/01/2002

### Completion date
30/06/2002

## Eligibility

### Key inclusion criteria
Healthy, nonsmoking, postmenopausal women were screened for regular soy consumption (less than or equal to one serving per day), vitamin C supplementation (less than or equal to 60 mg /day), and postmenopausal status (one year).

### Participant type(s)
Patient

### Age group
Adult

### Sex
Female

### Target number of participants
10

### Key exclusion criteria
1. Vegetarianism
2. Current or past diagnosis of cancer
3. Cardiovascular disease or diabetes
4. Chronic illness or inflammation
5. Gastrointestinal disorders
6. Recent (previous six months) use of antibiotics, and use of hypoglycaemic or hypolipidaemic medication
7. Body mass index (BMI) less than or equal to 35 kg/m^2
8. Consumed less than or equal to two alcoholic drinks per day

### Date of first enrolment
01/01/2002

### Date of final enrolment
30/06/2002

## Locations

### Countries of recruitment
United States of America

### Study participating centre
**Department of Nutrition**
Mesa
United States of America
85212

## Sponsor information

### Organisation
Arizona State University - Sustainable Technologies, Agribusiness and Resource Center (USA)

### Sponsor details
c/o John Brock
Center Coordinator
7001 East Williams Field Road
Arizona State University
Mesa
United States of America

85212
-
john.brock@asu.edu

**Sponsor type**
University/education

**ROR**
https://ror.org/03efmqc40

# Funder(s)

**Funder type**
University/education

**Funder Name**
Arizona State University - Sustainable Technologies, Agribusiness and Resource Center (USA)

# Results and Publications

**Publication and dissemination plan**
Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Other publications | case report | 23/06/2005 | | Yes | No |
| Results article | results | 01/07/2005 | | Yes | No |