

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

Submission date 04/01/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 24/02/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 19/09/2017	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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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 vacutainers, 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/m²
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

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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