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

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

Protocol serial number
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

Study type(s)
Treatment

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(s)
Lipid peroxides

Key secondary outcome(s))
1. Vitamin C
2. Total cholesterol, including LDL, HDL and Triglycerides (TG)
3. Blood pressure

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

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

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)

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

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?
Results article	results	01/07/2005		Yes	No
Other publications	case report	23/06/2005		Yes	No