

# Red clover-derived isoflavones and mammographic breast density: a double blind, randomised, placebo-controlled trial

<b>Submission date</b> 30/01/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/01/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 02/10/2012	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

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

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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MRC Dunn Human Nutrition Unit  
Cambridge  
United Kingdom  
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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N/A

## Study information

## Scientific Title

### Study objectives

To determine the effects of taking a red clover-derived isoflavone supplement daily for one year on mammographic breast density. Effects on oestradiol, follicle-stimulating hormone (FSH), luteinising hormone (LH), lymphocyte tyrosine kinase activity and menopausal symptoms were also assessed.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

All study procedures were approved by the Dunn Human Nutrition Unit Ethics Committee, and the Cambridge Local Research Ethics Committee.

### Study design

Randomised controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Hospital

### Study type(s)

Treatment

### Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

### Health condition(s) or problem(s) studied

Breast cancer

### Interventions

Red clover-derived isoflavone tablet (26 mg biochanin A, 16 mg formononetin, 1 mg genistein and 0.5 mg daidzein) or placebo.

### Intervention Type

Supplement

### Phase

Not Specified

### Drug/device/biological/vaccine name(s)

Red clover-derived isoflavone supplement

**Primary outcome measure**

Change in:

1. Mammographic breast density
2. Serum oestradiol, FSH and LH
3. Menopausal symptoms
4. Lymphocyte tyrosine kinase activity

Measured from baseline to 12 months.

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/05/1997

**Completion date**

31/12/1999

## Eligibility

**Key inclusion criteria**

1. Women aged 49 - 65 years
2. Wolfe's P2 or DY (dense parenchyma) mammographic breast patterns

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Female

**Target number of participants**

205

**Key exclusion criteria**

Not provided at time of registration.

**Date of first enrolment**

01/05/1997

**Date of final enrolment**

31/12/1999

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**  
**MRC Dunn Human Nutrition Unit**  
Cambridge  
United Kingdom  
CB2 2XY

## Sponsor information

**Organisation**  
Medical Research Council (UK)

**Sponsor details**  
20 Park Crescent  
London  
United Kingdom  
W1B 1AL

**Sponsor type**  
Research council

**ROR**  
<https://ror.org/03x94j517>

## Funder(s)

**Funder type**  
Industry

**Funder Name**  
Novogen Ltd (Australia)

**Funder Name**  
Medical Research Council (UK)

**Alternative Name(s)**  
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

**Funding Body Type**

Government organisation

### **Funding Body Subtype**

National government

### **Location**

United Kingdom

## **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?
<a href="#">Results article</a>	results	01/04/2004		Yes	No