ISRCTN42940165 https://doi.org/10.1186/ISRCTN42940165

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

| | | |
|---|---|---|
| **Submission date**<br>30/01/2004 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>30/01/2004 | **Overall study status**<br>Completed | |
| **Last Edited**<br>02/10/2012 | **Condition category**<br>Cancer | |

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

## Contact information

**Type(s)**
Scientific

**Contact name**
Dr Sheila A. Bingham

**Contact details**
MRC Dunn Human Nutrition Unit
Cambridge
United Kingdom
CB2 2XY

## Additional identifiers

**Protocol serial number**
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

## Study type(s)
Treatment

## 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(s)
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.

## Key secondary outcome(s))
Not provided at time of registration

## 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

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
Female

### 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
United Kingdom

England

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

# Sponsor information

### Organisation

Medical Research Council (UK)

**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, Medical Research Committee and Advisory Council, MRC

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

**Location**
United Kingdom

# 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 | 01/04/2004 | | Yes | No |