

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

Submission date 30/01/2004	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 30/01/2004	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 02/10/2012	Condition category Cancer	☐ 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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Additional identifiers

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.

Primary study design

Interventional

Study design

Randomised controlled trial

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