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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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/01/2004	**Overall study status** Completed	
Last Edited 02/10/2012	**Condition category** Cancer	

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

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?
Results article	results	01/04/2004		Yes	No