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Double-blind, placebo-controlled, randomised phase 2 trial of IH636 grape seed proanthocyanidin (GSPE) in patients with adverse effects of high dose breast radiotherapy

Submission date 15/10/2002	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 15/10/2002	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 05/01/2016	**Condition category** Cancer	[_] Individual participant data

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/using-ih636-grape-seed-extract-to-reduce-side-effects-of-high-dose-radiotherapy-for-breast-cancer

Contact information

Type(s)
Scientific

Contact name
Dr - -

Contact details
UKCCCR Register Co-ordinator
MRC Clinical Trials Unit
222 Euston Road
London
United Kingdom
NW1 2DA

Additional identifiers

Protocol serial number
RMH1991

Study information

Scientific Title
Double-blind, placebo-controlled, randomised phase 2 trial of IH636 grape seed proanthocyanidin (GSPE) in patients with adverse effects of high dose breast radiotherapy

Study objectives
Not provided at time of registration

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Double-blind placebo-controlled randomised study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Breast cancer

Interventions
IH636 grape seed proanthocyanidin extract (100 mg) or placebo TDS for 6 months

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
IH636 grape seed proanthocyanidin (GSPE)

Primary outcome(s)
Not provided at time of registration

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

Completion date
10/10/2002

Eligibility

Key inclusion criteria
1. Past history of early breast cancer (T1-3 N0-1 M0)
2. Past history of radiotherapy to the breast
3. A minimum of 24 months post radiotherapy
4. No evidence of cancer recurrence
5. Palpable breast induration due to previous radiotherapy
6. Ability to attend The Royal Marsden Hospital, Sutton for assessments
7. Written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Female

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/2001

Date of final enrolment
10/10/2002

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
MRC Clinical Trials Unit
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
The Royal Marsden NHS Foundation Trust (UK)

ROR
https://ror.org/0008wzh48

Funder(s)

Funder type
Research organisation

Funder Name
Royal Marsden Hospital (UK)

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	01/04/2006		Yes	No