

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 15/10/2002	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 05/01/2016	Condition category Cancer	<input type="checkbox"/> 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

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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

Study design

Double-blind placebo-controlled randomised study

Primary study design

Interventional

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