

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

|                                        |                                                   |                                                                                                   |
|----------------------------------------|---------------------------------------------------|---------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>15/10/2002   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>15/10/2002 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>05/01/2016       | <b>Condition category</b><br>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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United Kingdom  
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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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 01/04/2006   |            | Yes            | No              |