A Double Blind, Randomised, Placebo Controlled Study of Farlutal in the Treatment of Weight Loss in Patients Undergoing Radiotherapy for Head and Neck Cancer

Submission date	Recruitment status	Prospectively registered
19/08/2002	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
19/08/2002	Completed	Results
Last Edited	Condition category	Individual participant data
03/03/2008	Cancer	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

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

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Head and Neck Cancer

Interventions

- 1. Group A: Oral medroxyprogesterone acetate 500 mg twice daily for a maximum of 12 weeks
- 2. Group B: Placebo tablets twice daily for a maximum of 12 weeks

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

19/08/2000

Completion date

19/08/2005

Eligibility

Key inclusion criteria

- 1. Aged >18 years
- 2. Squamous cell carcinoma of the head and neck
- 3. Not known to have or suspected of having early breast cancer
- 4. No known hypersensitivity to medroxyprogesterone acetate
- 5. No medical contraindications to treatment

Participant type(s)

Patient

Age group

Not Specified

Lower age limit

18 Years

Sex

Not Specified

Target number of participants

Not provided at time of registration

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

19/08/2000

Date of final enrolment

19/08/2005

Locations

Countries of recruitment

England

Italy

United Kingdom

Study participating centre UKCCCR Register Co-ordinator London United Kingdom NW1 2DA

Sponsor information

Organisation

Farmitalia Carlo Erba (Italy)

Sponsor details

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16 - 1.

Italy

Sponsor type

Industry

ROR

https://ror.org/03htt2d69

Funder(s)

Funder type

Not defined

Funder Name

Not provided at time of registration.

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 summaryNot provided at time of registration