

A placebo-controlled, double-blind, multicentre phase III trial to assess the efficacy and safety of miltefosine solution in the treatment of breast cancer where no other appropriate treatment is available

Submission date 19/08/2002	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 19/08/2002	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 04/01/2012	Condition category Cancer	☐ Individual participant data

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

Protocol serial number
C121

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

Primary study design

Interventional

Study design

Multicentre randomised double blind placebo controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Breast cancer

Interventions

Patients are randomised to receive either:

1. Treatment A: Miltefosine, a 6% solution
2. Treatment B: Placebo solution

The solution whether placebo or miltefosine is applied to the affected area initially once daily (two drops per 10 cm surface area, allowing for an approximately 3 cm margin around the visible lesion). Provided this has good tolerability the dose will be escalated to twice daily applications from week two onwards. In the absence of clear progression of skin lesions or dose-limiting adverse events a minimum treatment time of eight weeks is suggested.

Patients who have a complete response should continue at the same dosage, if possible, for at least a further four weeks after the complete response is observed.

Patients will be treated and/or followed-up until progression or occurrence of skin lesions within the treated area, treatment stop due to poor tolerability of the study medication, or necessity for a change in systemic therapy.

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Miltefosine

Primary outcome(s)

Added 06/08/09:

Time to treatment failure

Key secondary outcome(s)

Added 06/08/09

1. Rate of response
2. Cutaneous reactions

Completion date

30/04/1998

Eligibility

Key inclusion criteria

1. Female, aged more than 18 years
2. Histologically or cytologically confirmed breast cancer with inoperable lesions, unsuitable for radiotherapy, inadequately manageable by radiotherapy or systemic endocrine or chemotherapy
3. Superficial nodular or "flat" skin lesions including (estimated depth 1 cm), at least one bidimensionally measurable and progressive lesion
4. Patients should have had at least one prior systemic endocrine or chemotherapy. Patients may take concomitant endocrine therapy only (endocrine therapy must have been unchanged for the last 12 weeks if ongoing at the time of study entry)
5. Performance status World Health Organisation (WHO) grade two with life expectancy of at least three months
6. Satisfactory haematological and blood chemistry values

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Female

Key exclusion criteria

1. Patients with no measurable lesions, skin lesions with estimated depth over 1 cm, ulcerated skin lesions over 10% of the area to be treated or local infection within the treated area
2. Clinical evidence of brain metastases that would limit life expectancy to less than six months
3. Patients with progressive associated systemic metastases
4. Previous malignancies within the last five years, except treated and cured carcinoma in situ of the cervix, non-melanoma skin cancer or cutaneous lymphepithelioma
5. Radiotherapy to skin lesions or chemotherapy within the last four weeks

6. Major surgery within the last two weeks

7. Uncontrolled clinically significant illness not related to cancer

The only permissible concomitant therapies are irradiation of non-skin lesions for symptom relief and endocrine therapy if it has remained unchanged for at least 12 weeks

Date of first enrolment

01/01/1998

Date of final enrolment

30/04/1998

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

UKCCCR Register Co-ordinator

London

United Kingdom

NW1 2DA

Sponsor information

Organisation

Cancer Research UK (CRUK) (UK)

ROR

<https://ror.org/054225q67>

Funder(s)

Funder type

Charity

Funder Name

Cancer Research UK (CRUK) (UK)

Alternative Name(s)

CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary****Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2001		Yes	No