ISRCTN91258120 https://doi.org/10.1186/ISRCTN91258120

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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

Study design
Multicentre randomised double blind placebo controlled trial

Primary study design
Interventional

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