A Randomized Phase II Study Of Reirradiation And Hyperthermia Versus Reirradiation And Hyperthermia Plus Chemotherapy For Locally Recurrent Breast Cancer In Previously Irradiated Area.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27367

Source
NTR

Brief title
ReHypCi

Health condition

recurrence breast cancer; Hyperthermia; Reirradiation; Cisplatin; PET-CT; recidief mammacarcinoom; Hyperthermie; herbestraling

Sponsors and support

Primary sponsor: Academic Medical Centre Amsterdam
department of Radiotherapy/ Radiation Oncology
prof. C.C.E.Koning
The Netherlands
Source(s) of monetary or material Support: fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

Local control rate.

Secondary outcome

1. Acute toxicity: Grade 4 dermatitis (ulceration/ necrosis), induced by treatment, requiring reconstructive surgery and/or hyperbaric oxygen;

2. Clinical complete response rate;

3. Disease free survival;

4. Overall survival;

5. Actuarial late toxicity.

Study description

Background summary

Patients with a local regional recurrence of invasive breast cancer in previously irradiated area treated with standard therapy consisting of radiotherapy and hyperthermia have a 3 year local control rate of 40%. In patients with inoperable local regional recurrences of breast cancer in previously irradiated areas subsequent local control is difficult to maintain with reirradiation only or combined with chemotherapy or hyperthermia. Effective treatment options are limited and as a consequence there is a high risk on subsequent failure and uncontrollable local disease. Moreover, progression of local regional recurrences may ultimately cause ulceration with odor, pain and bleeding resulting in considerable physical and mental suffering In view of the known radio enhancing effect of Cisplatin and the enhancement of Cisplatin and radiation effect by hyperthermia one might hypothesize that the combination of radiotherapy, hyperthermia and cisplatin can lead to improvement of local control, though toxicity may also be enhanced. Our department has experience with this trimodality treatment in esophageal cancer and uterine cervix cancer where it appears feasible. In the treatment of cervix cancer 40 mg/m2 CDDP once a week during radiotherapy is used currently. It seems worthwhile to evaluate the feasibility and efficacy of the combination of re-irradiation, hyperthermia and weekly Cisplatin for local regional recurrent breast cancer in previously irradiated area.

Study objective

To explore if there is an indication of a positive effect on local control rate of adding CDDP to local reirradiation and hyperthermia to patients with local regional recurrent breast cancer in previously irradiated area.

Study design

Patients will be seen 2, 4, 6 weeks and 3, 6, 9, and 12 months following completion of protocol therapy, or earlier in case of complaints or suspicion of recurrence. If CR or PR is assessed at one of these visits the patient will be seen 4 weeks after that visit for confirmation according to the RECIST criteria. After 1 year patients will be seen every 6 months. At each visit a digital photograph of the treated area is required. All toxicity will be measured by the treating physician according to the CTC criteria.

Intervention

Standard arm:

Radiotherapy/hyperthermia: 8 x 4 Gy to the affected area, two fractions per week, in combination with once weekly hyperthermia.

Study arm:

8 x 4 Gy to the affected area, two fractions per week, in combination with once weekly hyperthermia combined with Cispatin 40 mg/m² once per week. Cisplatin is given intravenously during the hyperthermia session.

Translational study on PET-CT: Minimum of 1 extra PET-CT scan, maximum of 5 extra PET-CT scans, only if the patient gives consent for this study!

Translational study on tumour biology: DNA Damage response and hypoxia: 2 x subcutaneous injection with Lidocaïne 2 %; 2 x biopsy of the tumour; 2 x measurement of hypoxia with the Eppendorf electrode, only if the patient gives consent for this study!

Contacts

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Eligibility criteria

Inclusion criteria

1. Macroscopic local regional recurrence of breast cancer in previously irradiated area, not suitable for resection;

2. Recurrence is measurable by clinical examination and/or radiological (CT-scan, MRI or ultrasound) assessment;

3. Confirmation of diagnosis of the local regional recurrence including all subtypes of invasive adenocarcinoma by histology or FNA (fine needle aspiration);

4. Local regional recurrence of breast cancer must be treatable with radiation and hyperthermia at the discretion of the treating physician (i.e. thickness ≤ 4 cm; cross-sectional diameter ≤ 30 cm);

5. Digital photograph of recurrence;

6. WBC ≥ 3,000; NG ≥ 1,000; platelets ≥ 100,000, ANC ≥ 1500;

7. Serum bilirubin ≤ 1.5 times upper limit of normal, transaminase ≤ 3 times upper limit of normal;

8. Calculated creatinine clearance > 60 ml/liter (Cockroft);

9. Distant metastases are allowed if life expectancy is ≥ 1 year i.e. limited bone metastases;

10. Concurrent endocrine/hormonal therapy is allowed;

11. ECOG performance score ≤ 2;

12. Written informed consent;

13. Patients must be older than 18 year;

14. Patient must not be pregnant or lactating. If appropriate effective contraception must be used.

Exclusion criteria

1. Concurrent chemotherapy other than study medication;

2. Uncontrolled infection;

3. Other previous malignancy that could conceivably be active;

4. Patients with pacemakers or implanted defibrillators on the same site as the treatment (if this is the case, the pacemaker or implanted defibrillator should be replaced if possible).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2011
Enrollment:	104

Type:	Anticipated

Ethics review

Positive opinion
Date: 07-01-2011
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 34632
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2564
NTR-old	NTR2682
CCMO	NL31630.018.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON34632

Study results

Summary results
N/A