Predicited 3D-SAR coverage: a prognostic indicator for treament outcome in superficial hyperthermia for breast cancer recurrences at the chest wall?

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON34847

Source
ToetsingOnline

Brief title
Predicted 3D-SAR coverage

Condition

- Other condition
- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
3D-SAR distribution, temperature- and energydistributions in breast cancer recurrence

Health condition

macroscopic breast cancer recurrence

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: KWF

Intervention

Keyword: energy- and temperature distributions, SAR dosimetry, superficial hyperthermia, thermal dose

Outcome measures

Primary outcome

Measured temperatures

Predicted SAR distributions

Predicted temperature distribution (both with generic and specific heat sink)

Secondary outcome

Complete response rate.

Local control.

Duration of control.

Toxicity.

Study description

Background summary

Within the hyperthermia (HT) community general consensus exists that quality of the HT treatment is a key factor for treatment outcome. In several clinical trials a correlation between treatment outcome and various retrospectively assessed thermal dose parameters has been demonstrated. In response we have, for many years, strongly invested in the continuous improvement of our systems for superficial HT (SHT). The latter has been very rewarding as we were able to double the complete response rate for large (diameter >3 cm) tumors from 31% to

65%. At the same time the average invasive tissue temperature increased by 1.3°C.
Major limitations for further enhancement of HT treatment quality lay in the difficulty to improve dosimetry and our inability to prospectively prescribe thermal dose. Important preconditions for solutions to overcome these limitations are that they must be *economically as well as clinically acceptable*. Especially for SHT the means to improve temperature monitoring are restricted. Overall, there exists the problem of interstitial thermometry: neither the patient nor the clinician appreciates increasing the density of interstitial temperature measuring points. Non-invasive thermometry (NIT) by MRI is not realistic for SHT and NIT by microwave radiometry or ultrasound has not been demonstrated to provide the required spatial resolution and temperature sensitivity. Hence, the only way to further enhance treatment quality of SHT is to leave the well-trodden paths, and consider new challenging and progressive solutions. Fortunately, the potential of electromagnetic models have increased dramatically. The presently available advanced HT treatment planning systems provide an excellent opportunity to calculate 3D SAR- or temperature distributions and derive predicted HT-dose parameters from these distributions. This opens the door for future prescription of HT-dose.

Study objective

The prime objective of the proposed study is to apply treatment modeling for superficial hyperthermia in a well-defined group of patients to investigate the potential of predicted 3-dimensional energy as source for a dose parameter that is prognostic for treatment outcome. Additionally, the energy distributions will be translated in generic and specific temperature distributions. Derivatives of these temperature distributions will be investigated on their prognostic potential also. If the project is successful, this will represent a major breakthrough for superficial hyperthermia, as it means that cumbersome and painful interstitial thermometry can be abandoned. This will render superficial hyperthermia more tolerable for cancer patients and for society will result in more economically profitable health care. Together, it will definitively boost the application of superficial hyperthermia.

Study design

In the regular RT+HT treatment protocol patients with recurrent breast cancer at the chest wall receive 8 RT-fractions and 4 HT-treatments in 4 weeks. Patients participating in this study will follow the same RT+HT treatment protocol. Prior to the first HT treatment the patient will get appointments for interstitial placement of the thermometry catheters and a CT-simulation scan of the chest wall specific for HT treatment planning plus exact localization of the position of the thermometry catheters.

Study burden and risks

To participate in the study is limited to only 30 minutes, what gives no extra risk or burden.

Contacts

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NL
Scientific
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Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

recurrent tumour of the chest wall, inoperable measurable tumour
tumour localisation on the chest wall
maximum extension in depth of the tumour not morer than 4cm
to obtain the design CT-simulation scan in hyperthermia position without contrast fluid
informed consent

Exclusion criteria

no possibility to place 3-4 interstitial thermometry catheters
inability to place the required number of Lucite Cone applicators
recurrence breast cancer not in previously irradiated area
not possible to make an CT-scan (claustrofobic)

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2007
Enrollment:	70
Type:	Anticipated

Ethics review

Approved WMO

Date:	10-10-2007
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL17787.078.07