SC.20 / CKTO 2004-06
A phase III international randomised trial of singel versus multiple fractions for re-irradiation of painful bone metastases.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20873

Source
NTR

Brief title
METRET (metastases retreatment trial)

Sponsors and support

Primary sponsor: -
Source(s) of monetary or material Support: for the Netherlands CKTO
for Canada NCIC
for USA RTOG
for Australia/NewZealand TROG
for UK

Intervention

Outcome measures

Primary outcome

To compare pain relief after re-irradiation of symptomatic bone metastases with 8 Gy or 20

Gy.

Secondary outcome

1. To determine the overall incidence of pain relief in patients undergoing re-irradiation for symptomatic bone metastases;

2. To determine the time to pain progression after re-irradiation;

To assess the relationship between response to initial radiation and pain relief with re-irradiation;

3. To determine the changes in functional interference following re-irradiation using the Brief Pain Inventory (and QoL using EORTC QLQ C30 in Canada and the Netherlands);

4. To determine the characteristics of the group of non-responders (to both the initial and re irradiation);

5. To monitor the incidence of acute severe radiation related side effects;

6. To monitor the incidence of in-field pathological fractures and spinal cord compression.

Study description

Background summary

N/A

Study objective

To study the effectivity of different retreatment radiotherapy schedules for painful bone metastases.

Study design

N/A

Intervention

ARM 1 - 8Gy

(single) „³ 1 fraction

ARM 2 - 20 Gy

(multiple) „· 5 fractions
„¹ 8 fractions (for spine and/or whole pelvis only)

Patients will be stratified by:

Their response to initial radiation as per physician's interpretation of patient history at the time of randomization into responders versus non-responders (i.e. patients who did or did not gain pain improvement after initial radiation);

Initial fractionation, i.e. single 6-8 Gy versus multiple fractions (20-24 Gy/5-6# and 30 Gy/10#);
Centre.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patient must be 18 years of age or older at the time of randomization;

2. Patient must have histologically or cytologically proven malignancy;

3. Histological diagnosis may be established from needle biopsy, bone marrow biopsy, cytology, or a surgical biopsy or resection;

4. All malignant histologies/cytologies are eligible;

5. Plain radiographs, radionuclide bone scans, CT scans and/or magnetic resonance imaging confirm the presence of bone metastases corresponding to clinically painful area;

6. Patient has a worst pain score of > 2/10 as reported using the Brief Pain Inventory;

7. There is no plan to make an immediate change in the analgesic regimen;

8. Karnofsky Performance Status > 50 within one week prior to randomization;

9. The interval between the last fraction of the initial radiation and the date of randomization in this study is > 4 weeks;

10. Initial radiation treatment field is reproducible for re-irradiation;

11. Pain is arising from the previously irradiated metastasis(es) and not from progressive disease in the adjoining or remote areas;

12. Site of pain considered for palliative radiotherapy must be encompassed by the same or smaller treatment field/portal as initial treatment;

13. Canada and The Netherlands only:

14. Patient is able (i.e. sufficiently fluent) and willing to complete the quality of life questionnaire in either English, French or Dutch. The baseline assessment must already have been completed;

15. Inability (illiteracy in English, French or Dutch, loss of sight, or other equivalent reason) to complete the questionnaires will not make the patient ineligible for the study. However, ability but unwillingness to complete the questionnaires will make the patient ineligible;

16. Patient consent must be obtained according to local Institutional and/or University Human Experimentation Committee requirements. It will be the responsibility of the local participating investigators to obtain the necessary local clearance, and to indicate in writing to the NCIC CTG Study Coordinator that such clearance has been obtained, before the trial can commence in that centre. Because of differing requirements, a standard consent form for the trial will not be provided but a sample form is given in Appendix XIII. A copy of the initial

full board REB approval and approved consent form must be sent to the central office;

17. The patient must sign the consent form prior to randomization or registration;

18. Please note that the consent form for this study must contain a statement which gives permission for the NCIC CTG and monitoring agencies to review patient records;

19. Patients must be accessible for treatment and follow-up. Investigators must assure themselves the patients randomized on this trial will be available for complete documentation of the treatment, adverse events, and follow-up;

20. In accordance with NCIC CTG policy, treatment must begin within 4 weeks of randomization.

Exclusion criteria

1. Clinical or radiological evidence of spinal cord compression at the time of assessment for this study;

2. Clinical or radiological evidence of pathological fractures of extremities in the area to be re-irradiated;

3. Radiological evidence of high-risk lesions for pathological fractures in the extremities (lytic lesions > 3 cm or > 50% cortical erosion of bone diameter) and candidate for surgical intervention. Patients who are NOT surgical candidates are eligible for this study;

4. The treatment area has received prior palliative surgery;

5. There is planned surgical intervention on the treated bone;

6. Treatment field of initial radiation volume has to be enlarged/modified to accommodate symptomatic disease not previously irradiated, or to provide adequate treatment margin;

7. Systemic radiotherapy (Sr-89) has been received within 30 days prior to randomization;

8. Patient has received half body irradiation including the current re-irradiation field within 30 days prior to randomization.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2005
Enrollment:	650
Type:	Actual

Ethics review

Positive opinion

Date:	12-09-2005
Application type:	First submission

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
NTR-new	NL320

Register	ID
NTR-old	NTR358
Other	: N/A
ISRCTN	ISRCTN48331851

Study results

Summary results
N/A