

**Respiratory Research Unit
North Bristol NHS Trust**

SMART Trial

**TRIAL SPECIFIC PROCEDURE
Version 4**

RADIOTHERAPY

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PATIENTS IN THE IMMEDIATE RADIOTHERAPY ARM

Timing of radiotherapy

For patients in the immediate (prophylactic) radiotherapy arm, radiotherapy should be given within 35 days of the pleural procedure for which the patient has been randomised. Under exceptional circumstances, the first fraction may be postponed for up to 42 days but a reason must be clearly stated.

Planning appointment:

All patients will attend a radiotherapy planning appointment with the clinical oncologist to plan and consent for the radiotherapy treatment (if consent has not already been obtained).

Technique:

The field should be marked with the patient in the most appropriate, reproducible and comfortable position for radiotherapy.

Volume to be treated:

For surgical and large bore pleural procedure scars, the total radiotherapy field is equivalent to the PTV (as defined below):

- Suggested Clinical Target Volume (CTV): chest drain and surgical sites/scars with at least a 3cm margin
- Suggested Planning Target Volume (PTV): CTV + 0.5cm if using kV photons or CTV +1cm if using electrons

For patients with an indwelling pleural catheter in situ, the radiotherapy field is equivalent to the PTV (as defined below):

- Suggested Clinical Target Volume (CTV): pleural puncture site, the whole of the catheter tract and the skin exit site with at least a 3cm margin
- Suggested Planning Target Volume (PTV): CTV + 0.5cm if using kV photons or CTV +1cm if using electrons

The volume to be treated must be acceptable to the treating clinical oncologist.

Diagnostic CT scans can be used to assess treatment depth to the chest wall. The treatment area should be no less than 7cm in any one direction.

Shielding can be used as appropriate, as long as this does not compromise the above treatment margins.

If matching fields are required due to the site and position of the scars, then use clinical discretion and follow your local policies, for example match the 50% edge of fields.

Beam Arrangement:

A single direct beam will be used in the majority of cases. If an alternative beam arrangement is considered necessary then it must be documented on the Clinical Record Form (CRF).

Dose:

21Gray in 3 fractions over 3 working days prescribed following normal departmental procedures for electrons or applied if using kV photons. This dose should not be given over spinal cord, but if any concern regarding this then the dose may need to be altered and recorded on the Clinical Record Form (CRF).

Energy:

The preferred procedure is that patients are treated using electrons, of appropriate energy to treat the chest wall to at least 90%. Kilovoltage (kV) photons (minimum 220kV) can be used if electrons are not available as long as the depth to chest wall is adequate. Where it is necessary due to bulky chest wall or pleural disease, megavoltage photons (MV) can be used as clinically appropriate.

Bolus:

Bolus should be used as necessary to ensure that the skin dose is at least 90%.

Record:

The radiotherapy given should be recorded in the patient's clinical notes. It is good clinical practice for centres to photograph the radiotherapy field at the first session to ensure patient position and fields for subsequent fractions are similar. If this is usual practice at the individual radiotherapy centre, a photograph will be taken but this is not a requirement for the trial and the photograph will not be forwarded to the trial team.

In addition, the details should be completed on the radiotherapy CRF, to include the total dose, number of treatment fractions, number of days of treatment course, field size, type and dose of energy used, whether bolus or shielding was used, protocol deviations and any side effects noted during the radiotherapy course.

The CRF should be returned to the trial team at the recruiting centre.

PATIENTS IN THE DEFERRED RADIOTHERAPY ARM WHO DEVELOP A PROCEDURE TRACT METASTASIS

Timing

For patients in the deferred radiotherapy arm, radiotherapy should be given within 35 days of a PTM being confirmed at the clinic visit.

Planning appointment:

All patients will attend a radiotherapy planning appointment with the clinical oncologist to plan and consent for the radiotherapy treatment (if consent has not already been obtained in a clinic).

Technique:

The field should be marked with patient in the most appropriate, reproducible and comfortable position for radiotherapy.

Volume to be treated:

The total radiotherapy field is equivalent to the PTV (as defined below):

- Suggested Clinical Target Volume (CTV): palpable nodule with at least a 2cm margin
- Suggested Planning Target Volume (PTV): CTV + 0.5cm if using kV photons or CTV +1cm if using electrons

The volume to be treated must be acceptable to the treating clinical oncologist.

Diagnostic CT scans can be used to assess treatment depth to the chest wall. Shielding can be used as appropriate, as long as this does not compromise the above treatment margins.

If matching fields are required due to the site and position of nodules, then use clinical discretion and follow your local policies, for example match the 50% edge of fields.

Beam Arrangement:

A single direct beam will be used in the majority of cases. If an alternative beam arrangement is considered necessary then it must be documented on the Clinical Record Form (CRF)

Dose:

21Gray in 3 fractions over 3 working days prescribed following normal departmental procedures for electrons or applied if using kV photons. This dose should not be given over the spinal cord, but if there is any concern regarding this then the dose may need to be altered and recorded on the CRF.

Energy:

The preferred procedure is that patients are treated using electrons, of appropriate energy to treat the chest wall to at least 90%. Kilovoltage (kV) photons (minimum 220kV) can be used if electrons are not available as long as the depth to chest wall is adequate. Where it is necessary due to bulky chest wall or pleural disease, megavoltage photons (MV) can be used as clinically appropriate.

Bolus:

Bolus should be used as necessary to ensure that the skin dose is at least 90%.

Record

The radiotherapy given should be recorded in the patient's clinical notes. It is good clinical practice for centres to photograph the radiotherapy field at the first session to ensure patient position and fields for subsequent fractions are similar. If this is usual practice at the individual radiotherapy centre, a photograph will be taken but this is not a requirement for the trial and the photograph will not be forwarded to the trial team.

In addition, the details should be completed on the radiotherapy CRF, to include the total dose, number of treatment fractions, number of days of treatment course, field size, type and dose of energy used, whether bolus or shielding was used, protocol deviations and any side effects noted during the radiotherapy course.

The CRF should be returned to the trial team at the recruiting centre.

PATIENTS IN THE IMMEDIATE RADIOTHERAPY ARM WHO DEVELOP A PROCEDURE TRACT METASTASIS

For patients in the immediate radiotherapy arm, further radiotherapy treatment if a procedure tract metastasis develops will be at the discretion of the oncologist. The treatment given should be recorded on the SMART trial radiotherapy CRF, which should then be returned to the trial team.

In order to establish whether the tract metastasis is within the previous radiotherapy field, on the edge of the field or distant to the radiotherapy field, the clinician should ideally have access to the clinical photograph taken at the time of radiotherapy.

RADIOTHERAPY FOR OTHER INDICATIONS

For patients who are enrolled in the SMART trial who require radiotherapy for another indication, the radiotherapy regime is at the discretion of the oncologist responsible for the patient's care. However, if the radiotherapy given is within a 10cm margin of the procedure site, it should be recorded on a SMART trial radiotherapy CRF, which should then be returned to the trial team.

TOXICITY AND FOLLOW UP

In all patients who have received chest radiotherapy during the trial follow up period, skin toxicity will be assessed at all clinical follow up visits using RTOG/EORTC toxicity grading. Patients will be asked about other side effects by completing a questionnaire at the clinic visit after the radiotherapy is given.

FURTHER ADVICE

If further radiotherapy advice is required regarding treatment planning or complex cases, clinicians are encouraged to liaise directly with the trial clinical oncologists, who are happy to give advice on a case by case basis.

Their contact details are:

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