Clinical Guideline for Administration of Molecular Radiotherapy

Version 2 2019

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Contents

This guideline must be read in conjunction with other BNMS guidelines.

1. Purpose

The purpose of this guideline is to define quality standards for the administration of Molecular Radionuclide Therapy (MRT). This guideline should be used to help individual departments formulate their own local protocols and assist commissioners seeking to understand and establish quality and performance standards for Molecular Radionuclide Therapy services.

2.Background

Molecular radionuclide therapy is given by administering a radiopharmaceutical (a radiation source attached to a drug or chemical) which will then concentrate, in, or near a target area e.g. a tumour. For example, ^{131}Iodine- is readily taken up in thyroid tissue and is used to treat thyroid cancer and non-malignant thyroid disorders.

Therapeutic procedures can also be palliative, usually to relieve pain. For instance, ^{89}Strontium and ^{153}Samarium and ^{186}Rhenium- are used for the relief of cancer-induced bone pain. Neuroendocrine tumours can be treated with ^{177}Lutetium- Dotatate or Octreotate.

A growing field is the use of ^{223} Radium-dichloride (an alpha emitter) in the treatment of metastatic prostate cancer.

For all therapeutic procedures, the employing organisation has a responsibility to provide good patient care within a stringent clinical governance framework. In addition, organisations must ensure adequate precautionary measures are put in place to comply with relevant legislation and to ensure that radiation risks are minimised to: staff, other workers, relatives, carers and the general public.

3.List of Molecular Radiotherapy Isotopes

Radionuclide	**Clinical indication**
^{131}Iodine	
^{131}Iodine Iodide	Benign thyroid disease : Thyrotoxicosis
^{131}Iodine Iodide	Benign thyroid disease : Non-toxic goitre
^{131}Iodine Iodide	Carcinoma of thyroid
^{131}Iodine- MIBG	Other malignant disease (Neuroendocrine tumours)
^{223}Radium	
^{223}Radium Dichloride	Pain relief from bone metastases
^{89}Strontium	
^{89}Strontium- chloride	Pain relief from bony metastases
^{153}Samarium	
^{153}Samarium EDTMP	Pain relief from bony metastases
^{169}Erbium-colloid	Synovectomy
^{186}Rhenium	
^{186}Rhenium- colloid	Pain relief from bony metastases
	Synovectomy
^{177}Lutetium	
^{177}Lutetium-PRRT (Peptide Receptor Radionuclide Therapy	Neuroendocrine tumours (NETs) (peptides – Dotatate, Dotanoc

^{177}Lutetium-PSMA (Prostate Specific Membrane Antigen)	Prostate Cancer
^{32}Phosphorous	
^{32} Phosphorous –Phosphate	Polycythemia Vera and related disorders
^{90}Yttrium	
^{90}Yttrium - colloidal silicate/citrate	Arthritic conditions
^{90}Yttrium - Microspheres	Hepatic malignancy
^{90}Yttrium - PRRT	Neuroendocrine Tumours (peptides – dotatate, dotanoc,
^{90}Yttrium- *Zevalin*	Non-Hodgkins Lymphoma

4.Contraindications

1. Absolute: Pregnancy
2. Absolute: Breastfeeding
3. Relative: Pathology which has a predominantly osteoclastic process resulting in lytic lesions such as multiple myeloma which are unlikely to concentrate the tracer
4. Relative: Trauma or surgery to the region of interest in the previous 6-12 months due to inability of osteoblastic activity relating to normal post-traumatic or post-operative resolution to be distinguished from that due to postoperative complications.

5.Key Duty Holders

Prior to the introduction of MRT, the organisation wanting to undertake this must ensure the following key duty holders have been appointed

Key Duty Holder	**Responsible for**	**Knowledge and skills/Certification**	**On site during MRT**
Practitioner* (ARSAC holder)	The clinical aspects of the treatment including justifying the administration	ARSAC certificate for therapies being performed	Contactable for all. Present for research, complex or novel therapies
Radiation Protection Advisor(RPA)	Advise employer on compliance with IRR17	RPA2000	No
Radiation Protection Supervisor* (RPS)	Local rules, radiation safety culture, monitoring under IRR17	Local training. Formal appointment	Contactable
Medical Physics Expert* (MPE)	Optimisation, dosimetry equipment QA, compliance with IRMER18	Registered by RPS2000	Contactable for all. Present for research, complex or novel therapies as defined in regulations

Radioactive Waste Advisor (RWA)	Accumulation, storage and disposal of radioactive materials	RWA certified by RPA2000	No
Operators	Administering the radiopharmaceutical Defined in IRMER2018	Local training	Yes

* Some procedures may involve a combination of imaging and MRT. There need to be clear identification of duty holders and lines of accountability for each function. Duty holders should be appointed in writing by the employer.

All staff involved with the MRT should be trained to fulfil their specific role and should ensure that they are able to maintain their competence and undertake relevant Continuing Professional Development (CPD) activities. Key duty holder must be registered Healthcare Professionals (HCP) (or on a voluntary register) and certified (where applicable).

6.Dosimetry and Optimisation of Radiation Exposure

The administered activity per administration is a matter for clinical judgment based on the expert knowledge of the ARSAC licence holder. Caution is advised in treatment for non- malignant disease and especially in young patients**.** MRT is usually requested by a referring clinician (who may be the Practitioner) who has assessed the patient clinically and understands their role under IRMER18. Sometimes (especially in the context of cancer) a multidisciplinary meeting is held where the decision to offer MRT is made. For complex, non-standard or novel MRT treatments optimisation of the radiation exposure will be required and the MPE for the service should be involved in the multidisciplinary discussions. Adequate records of the decision to treat should be kept in the patients records. The administered activity should be justified by the ARSAC licence holder (practitioner under IRMER). ARSAC holders should follow established evidence based guidelines for each procedure, varying from these according to specific clinical circumstances.

The effective dose from radionuclide therapy will depend on the radiopharmaceutial, activity administered and the anatomy and physiology of the patient. The MPE should be involved in agreeing the protocols for MRT and agreeing variance to standard practice. Regular audit should be performed to ensure good practice. Novel or non-standard procedures will require the MPE to optimise the effective dose for the treatment and provide personalised patient dosimetry for the procedure where applicable. The results should be discussed with the ARSAC licence holder prior to treatment. Where appropriate and practical, patient dosimetry should be performed. The effective dose and the clinical evaluation should be documented in the patient's record.

7.Accumulation and storage of radioactive materials and management of radioactive waste

Systems should be in place to ensure there are suitable permits in place from the relevant UK environment agency to cover the storage of material and waste accumulation and disposal. A Quality Management System covering these aspects is recommended to demonstrate compliance.

8.Patient preparation

Patient preparation will vary depending on the type of therapy. Therapy protocols must be written (following national guidelines or an evidence base) and signed off by the ARSAC practitioner and the MPE. This will require a multi-disciplinary approach to ensure that all HCPs involved with patient care understand and agree with the preparation. Good quality communication supplemented by well written patient information leaflets are critical to ensure the patients understand and comply with any requirements. Written consent should be obtained prior to administration and checked by the HCP performing the administration. Every patient receiving MRT requires written information on radiation protection guidance post treatment to optimise their treatment and minimise radiation exposure to relatives and members of the public. Any written information must be agreed by the MPE with advice by the ARSAC licence holder(s).

9.Training for Administration of MRT

All staff involved in the MRT must have appropriate training for the functions they are going to perform. The training of personnel to administer radiotherapy radionuclides should be standardised within the administration centre. The required training package should be agreed with the key duty holders and this should include a competency assessment. All staff should maintain a training record to demonstrate initial training, ongoing competence and CPD.

Staff training records should be held within the Trust along with a list of personnel able to administer therapies as per IRMER regulations. Specific procedures should be drawn up and personnel should not deviate from the procedures without reference to the ARSAC practitioner.

10.Administration of MRT

The MRT may be administered directly by the ARSAC practitioner or by another HCP (doctor, nurse, radiographer, scientist or technologist) under delegated authority from an ARSAC licence holder. The person administering MRT should be adequately trained in the procedure according to local and national standards where present. Research, novel or complex MRT should be undertaken directly by the ARSAC licence holder and MPE. If this is not possible, others acting under delegated authority can administer MRT if their training and ability is considered adequate by the ARSAC licence holder.
The clinical condition of the patient can change between referral for therapy and day of administration. E.g. through medication withdrawal. This potentially will need re-justification of the referral on the day by an ARSAC licence holder or delegated clinician following a written system of work. There should be good working relationships between the referring clinical team and the administering team. A system should be in place for resolving clinical issues not related to MRT occurring at the time of treatment.

11.Unexpected occurrences

Organisations performing MRT need to have contingency plans in place to cope with the following;

- Adverse reactions
- Extravasation
- Clinical issues not related to MRT
- Deteriorating patient
- Re-admission to a healthcare establishment
- Death of a patient
- Reasonably foreseeable accidents involving radioactive materials

Whilst every effort has been made to ensure the BNMS provides accurate and expert information and guidance, it is impossible to predict all the circumstances in which it may be used. Accordingly the BNMS shall not be liable to any person or entity with respect to any loss or damage caused or allege to be caused directly or indirectly by what is contained in or left out of this guidance.

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12.Version & Review

Comment	Date	Version	Reviewer
Initial draft first posted	June 2017	V1	
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