Systemic Anti Cancer Therapy Protocol

Clinical Verification of Radium-223 in Prostate cancer

PROTOCOL REF: MPHACVRUR
(Version No: 1.1)

This protocol has been temporarily amended – please refer to the SRG Guidelines during COVID-19 Urology Cancer.

Approved for use in:

- **Please note this document is for pharmacy use only**
- Monotherapy or combination with a LHRH analogue for the treatment of patients who have metastatic hormone-relapsed prostate cancer (mHRPC), symptomatic bones metastases and no known visceral metastases.
- Disease progression after at least two prior lines of systemic therapy (excluding LHRH analogues) or ineligible for any systemic mHRPC treatment.
- Performance status 0-2
- ARSAC certificate holder must approve treatment on Meditech

Blueteq registration required: see blueteq for full eligibility criteria

Dosage:

Drug	Dose	Route	Frequency
Radium-223	**55kBq per kg body weight**	IV injection	Every 28 days

Maximum of 6 cycles

Weight must be recorded at each cycle; dose can be calculated using patient's previous weight taken (which must not be older than 4 weeks).

Administration:

Please note Radium-233 is stored and prepared within the nuclear medicines department.

Please refer to Radiotherapy guideline- Radium-223 dichloride therapy protocol

Extravasation risk:

Refer to the CCC policy for the 'Prevention and Management of Extravasation Injuries'

Dosing in renal and hepatic impairment:

Renal	Excretion in urine is minimal and the major route of elimination is via the faeces, renal impairment is not expected to affect the pharmacokinetics of radium-223 dichloride. No dose adjustment is considered necessary in patients with renal impairment.

Hepatic	Radium-223 is not metabolised by the liver or eliminated via the bile, hepatic impairment is not expected to affect the pharmacokinetics of radium-223 dichloride. No dose adjustment is considered necessary in patients with hepatic impairment.

Interactions:

- Contraindicated in combination with abiraterone acetate and prednisolone, there is also evidence that the risk of skeletal fractures is increased with the combination of enzalutamide and radium-223; hence the combination of radium-223 with other systemic cancer therapies other than LHRH analogues is not recommended.
- It is recommended to administer zoledronic acid, calcium and vitamin D supplements concurrently with radium-223 as the risk of fractures is reduced.

Treatment schedule:

Please refer to radiotherapy protocol - Radium-223 dichloride therapy protocol

Main toxicities:

System Organ Class	Very common	Common	Uncommon
Blood and lymphatic system disorders	Thrombocytopenia	Neutropenia Pancytopenia Leukopenia	Lymphopenia
Gastrointestinal disorders	Diarrhoea Vomiting Nausea		
Musculoskeletal and connective tissue disorders	Bone fracture		Osteoporosis

Dose Modifications and Toxicity Management:

Complete this guidance in line with SPC/ other protocols or trial protocols.

Haematological toxicity:

Proceed on day 1 if-

ANC ≥ 1.5 x 10^9/L	Plt ≥ 100 x 10^9/L	Hb > 10*

Before cycle 2-6-

ANC ≥ 1.0 x 10^9/L	Plt ≥ 50 x 10^9/L	Hb > 10*

*** Transfuse if appropriate**

In case there is no recovery in these values within 6 weeks after the last administration of radium-223 despite receiving standard of care, further treatment with radium-223 should only be continued if this is approved by the consultant.

References:

1. EMC. *Xofigo 1100kBq/ml solution*. Available from: https://www.medicines.org.uk/emc/product/5204
2. NICE. *Radium-223 dichloride for treating hormone relapsed prostate cancer with bone metastases*. Available from: https://www.nice.org.uk/guidance/ta412
3. CCC radiation services quality system. Radium-223 dichloride therapy protocol
4. CCC work instruction- Electronic referral/prescription & ordering process for radium.
5. CCC electronic referral/prescription ordering and booking process for radium -223