Lancashire & South Cumbria Cancer Network
Systemic Anticancer Treatment Protocol

DRUG REGIMEN
Cabazitaxel and Prednisolone

Indication for use
Hormone refractory metastatic prostate cancer (HRPC) previously treated with docetaxel containing regimen

Eligibility
Disease progression during or after docetaxel containing regimen for HRPC
PS 0-2
Adequate bone marrow, liver and kidney function

Exclusions
Prior radiotherapy to >40% bone marrow
Any radiotherapy within 7 days
Prior radionucleotide therapy with samarium-153 or P-32 within 8 weeks or strontium-89 or radium-223 within 12 weeks
Prior surgery or chemotherapy within 4 weeks
Active grade ≥2 neuropathy
Active grade ≥2 stomatitis
Severe hypersensitivity to docetaxel or Polysorbate 80
Severe illness
Active infection
Prior treatment with potent inhibitors or inducers of P450 3A4 or 3A5

Regimen

Premedication
30 minutes prior to each administration:
Antihistamine Chlorphenamine – 10mg IV
Steroid – Dexamethasone 8mg IV
H_2 Antagonist – Ranitidine – 50mg IV

Cabazitaxel 25mg/m^2 IV in 250ml 0.9% NaCl over1 hour
Prednisolone – 10mg orally once daily continuous

Give every 3 weeks until disease progression (maximum 10 cycles)

Primary prophylaxis with GCSF should be considered in patients with high-risk factors for prolonged neutropenia (age >65, poor PS, previous episodes of febrile neutropenia, extensive prior radiation ports, poor nutritional status, other comorbidities)

Prescribe loperamide with first cycle

Investigation prior to initiating treatment
FBC, U&Es, LFTs

Cautions
Bilirubin > 1 ULN
AST/ALT >1.5 ULN
Creatinine Clearance <30ml/min

Investigations and consultations prior to each cycle
Consultation prior to each cycle
FBC, U&Es, LFTs, PSA, LDH
Monitor FBC weekly for the 1st cycle

Acceptable levels for treatment to proceed (if outside these levels defer one week or contact consultant)
Neutrophil count >1.5/mm^3, Platelets >100

Side Effects
Hypersensitivity reaction
Neutropenia, anaemia, thrombocytopaenia
Nausea, Vomiting
Diarrhoea, Dehydration
Cardiac arrhythmias
Haematuria
Fatigue
Pyrexia

Dose Modification Criteria
Nausea/vomiting – replace metoclopramide pre-med with ondansetron. If, despite this grade ≥3 nausea/vomiting occurs then reduce dose to 20mg/m^2. Withdraw treatment if this recurs

Diarrhoea:
- Grade ≥3 – delay treatment until resolved then restart at 20mg/m^2; if diarrhoea recurs at grade ≥3 at reduced dose then withdraw treatment

Stomatitis:
- Grade 3 – withhold treatment until grade 1 then restart at 20mg/m^2
- Grade 4 – withdraw treatment

Peripheral neuropathy:
- Grade 1 – no change
- Grade 2 – Reduce dose to 20mg/m^2
- Grade 3 – withdraw treatment

Neutropenia ≥ 7 days or febrile neutropenia:
- 1st episode - withhold treatment until resolved then resume treatment
- 2nd episode – reduce dose to 20mg/m^2
- 3rd episode – withdraw treatment

Thrombocytopenia:
- Grade 3 – delay until resolved
- Grade 4 – delay until resolved and reduce dose to 20mg/m^2; withdraw in case of recurrence

Liver toxicity – if AST/ALT >1.5x ULN or bilirubin >ULN then delay until resolved and reduce dose to 20mg/m^2

If treatment delayed > 2 weeks for any toxicity then withdraw therapy

Specific Information on Administration
Avoid medicinal products that are strong inducers or inhibitors of CYP3A
Prescribe TTO loperamide with cycle 1. Instruct patient to take at onset of diarrhoea and to contact chemotherapy helpline
Infuse via a 0.2µm in-line filter

THIS PROTOCOL HAS BEEN DIRECTED BY DR BIRTLE, CLINICIAN FOR UROLOGICAL CANCER

RESPONSIBILITY FOR THIS PROTOCOL LIES WITH THE HEAD OF SERVICE

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