Chemotherapy Protocol

PROSTATE

DOCETAXEL(30)-PREDNISOLONE

Regimen

- Prostate-Docetaxel (30)-Prednisolone

Indication

- Advanced castrate resistant prostate cancer
- Performance status 0, 1, 2

Toxicity

Drug	Adverse Effect
Docetaxel	Hypersensitivity, fluid retention, neuropathy, joint pains, nail changes, fatigue
Prednisolone	Weight gain, GI disturbances, hyperglycaemia, CNS disturbances, cushingoid changes, osteoporosis

The adverse effects listed are not exhaustive. Please refer to the relevant Summary of Product Characteristics for full details.

Monitoring

Drugs

- FBC, LFTs, PSA and U&Es prior to each cycle

Dose Modifications

The dose modifications listed are for haematological, liver and renal function and drug specific toxicities only. Dose adjustments may be necessary for other toxicities as well.

In principle all dose reductions due to adverse drug reactions should not be re-escalated in subsequent cycles without consultant approval. It is also a general rule for chemotherapy that if a third dose reduction is necessary treatment should be stopped.

Please discuss all dose reductions / delays with the relevant consultant before prescribing, if appropriate. The approach may be different depending on the clinical circumstances.

Haematological

Consider a blood transfusion if patient symptomatic of anaemia or has a haemoglobin of less than 8g/dL.

Prior to cycle one the following criteria should be met;

Criteria	Eligible Level
Neutrophils	$1x10^9$/L or greater
Platelets	$50x10^9$/L or greater

Dose modifications based on haematological parameters apply to docetaxel only. In general this regimen should be stopped in response to toxicity rather than the doses modified.

Hepatic Impairment

Drug	Bilirubin (µmol/L)		AST/ALT (units/L)		Alk Phos (units/L)	Dose (% of original dose)
Docetaxel	N/A		greater than 1.5xULN	and	greater than 2.5xULN	Give 75%
	greater than ULN	and/ or	greater than 3.5xULN	and	greater than 6xULN	Not Recommended

Renal Impairment

Drug	Creatinine Clearance (ml/min)	Dose (% of original dose)
Docetaxel	N/A	No dose adjustment needed

Other

Dose reductions or interruptions in therapy are not necessary for those toxicities that are considered unlikely to be serious or life threatening. For example, alopecia, altered taste or nail changes.

For all other non-haematological NCI-CTC grade 3 and above toxicities delay treatment until the adverse effect has resolved to NCI-CTC grade 1 or below. In general this regimen should be stopped in response to toxicity rather than the doses modified or the cycle length extended.

Regimen

42 day cycle for 5 cycles

Drug	Dose	Days	Administration
Docetaxel	30mg/m^2	1, 8, 15, 22, 29	Intravenous infusion in 250ml sodium chloride 0.9% over 60 minutes
Prednisolone	5mg twice a day	1-42 incl.	Oral

Dose Information

- Docetaxel will be banded as per the CSCCN agreed bands.
- Docetaxel induced fluid retention can lead to weight gain. This is not a reason to alter the doses
- Prednisolone is available as 5mg (uncoated) and 2.5mg and 5mg (enteric coated) tablets.

Administration Information

- Docetaxel hypersensitivity reactions tend to occur with the first or second infusion. For minor symptoms such as flushing or localised rashes the infusion should not be interrupted. For severe reactions including profound hypotension, bronchospasm and generalised erythema discontinue the infusion immediately.
- Prednisolone should be taken with or after food.

Extravasation

- Docetaxel - exfoliant

Additional Therapy

- Premedication
- Antiemetics

  15-30 minutes prior to chemotherapy

  - dexamethasone 8mg oral or intravenous
  - metoclopramide 10mg oral or intravenous

  As take home medication

  - metoclopramide 10mg oral three times a day for 3 days then as required

Additional Information

- Patients who stop docetaxel may require gradual withdrawal of the prednisolone

Coding (OPCS)

Procurement – X70.3

- Delivery – X72.3 & X72.4

References
1.Tannock IF, deWit R, Berry WR et al. Docetaxel plus prednisone or mitoxantrone plus prednisone for advanced prostate cancer. N Engl J Med 2004; 351 (15): 1502-1512.
2.NICE Guidance TA101. Docetaxel for the treatment of hormone refractory metastatic prostate cancer; June 2006.
3.Fossa SD. A randomised phase II trial comparing weekly Taxotere plus prednisolone versus prednisolone alone in androgen independent prostate cancer. Front Radiat Ther Oncol 2008; 41: 108-116.

REGIMEN SUMMARY

Docetaxel (30)-Prednisolone

Day 1, 8, 15, 22, 29

1. Dexamethasone 8mg oral or intravenous

2. Metoclopramide 10mg oral or intravenous

3. Docetaxel 30mg/m^2 in 250ml sodium chloride 0.9% intravenous infusion over 60 minutes

Take Home Medicines (Day 1 only)

4. Prednisolone 5mg twice a day oral for 42 days
   Administration Instructions
   Take with or after food. The dose of this medicine may need to be reduced gradually before stopping treatment.

5. Metoclopramide 10mg oral three times a day when required for nausea.
   Administration Instructions
   Please supply 60 tablets or two original packs as appropriate

DOCUMENT CONTROL

Version	Date	Amendment	Written By	Approved By
1.1	May 2015	Metoclopramide dose changed to 10mg Bolus removed from intravenous bolus throughout text Hepatic impairment info and table updated Information re doses above 200mg removed Prednisolone admin instructions updated. OPCS codes updated Disclaimer updated	Donna Kimber Pharmacy Technician	Rebecca Wills Pharmacist
1	May 2013	None	Dr Deborah Wright Pharmacist	Dr Joanna Gale Consultant Medical Oncologist Dr Mathew Wheater Consultant Medical Oncologist

This chemotherapy protocol has been developed as part of the chemotherapy electronic prescribing project. This was and remains a collaborative project that originated from the former CSCCN. These documents have been approved on behalf of the following Trusts;

Hampshire Hospitals NHS Foundation Trust
NHS Isle of Wight
Portsmouth Hospitals NHS Trust
Salisbury Hospitals NHS Foundation Trust
University Hospital Southampton NHS Foundation Trust
Western Sussex Hospitals NHS Foundation Trust

All actions have been taken to ensure these protocols are correct. However, no responsibility can be taken for errors which occur as a result of following these guidelines.