Chemotherapy Protocol

GYNAECOLOGICAL CANCER

GEMCITABINE

Regimen

- Ovarian – Gemcitabine

Indication

- The treatment of advanced ovarian cancer
- WHO Performance status 0, 1, 2

Toxicity

Drug	Adverse Effect
Gemcitabine	Diarrhoea, constipation, rash, respiratory problems (pneumonitis), influenza like symptoms, radiosensitising, transient elevation of LFTs

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

Monitoring

Drugs

- FBC, U&E's and LFT's prior to each treatment (days 1, 8, 15).

Dose Modifications

The dose modifications listed are for haematological, liver and renal function 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. The following is a general guide only.

Haematological

Prior to prescribing cycle one the following criteria must be met.

Criteria	Eligible Level
Neutrophil	equal to or more than $1.5x10^9$/L
Platelets	equal to or more than $100x10^9$/L

Consider blood transfusion or erythropoietin according to NICE criteria if the patient is symptomatic of anaemia or has a haemoglobin of less than 8g/dL

On the day of gemcitabine administration, if the neutrophils are 0.5–1x10^9/L and/or the platelets 50-100x10^9/L then administer 75% of the original dose. If the neutrophils are less than 0.5x10^9/L and the platelets are less than 50x10^9/L omit the gemcitabine for 7 days.

Patients who have had a dose reduction due to decreased neutrophil or platelet count should have their next dose according to neutrophil and/or platelet count on the day of gemcitabine administration, i.e. they can have their dose escalated back to 100% dose if their blood count is adequate. However, if after dose reduction to 75%, their blood count on the day of the next gemcitabine administration is still inadequate i.e. neutrophil count between 0.5-1x10^9/l or platelet count between 50-100x10^9/l the same dose (dose reduction to 75% of original dose) should be given.

Where dose omissions occur the dose should not be replaced and patients should maintain the same cycle schedule.

Hepatic Impairment

Drug	Bilirubin (µmol/L)		AST/ALT	Dose (% of original dose)
Gemcitabine	Consider dose reductions especially where the bilirubin is raised			

Renal Impairment

Drug	Creatinine Clearance (ml/min)	Dose (% of original dose)
Gemcitabine	Consider dose adjustments when the CrCl is less than 30ml/min	

Other

If an episode of neutropenic sepsis occurs, all subsequent courses should be subject to the following dose adjustments. The gemcitabine should be withheld until the patient has fully recovered and then re-instated at 75% of the original dose with no further re-escalation. If this occurs in a patient already receiving 75% of the full dose, then a further dose reduction to 50% of the full dose should be made.

Modifications are not usually required for other non-haematological toxicities. In exceptional cases, treatment delay may be necessary until the toxicity has resolved. If this happens, a 25% dose reduction should be made for all subsequent courses.

Regimen

28 day cycle for 6 cycles

Drug	Dose	Days	Administration
Gemcitabine	1000mg/m^2	1, 8, 15	Intravenous infusion in 250ml sodium chloride 0.9% over 30 minutes

Dose Information

- Gemcitabine will be dose banded as per the CSCCN agreed bands.

Administration Information

Extravasation

- Gemcitabine – neutral

Additional Therapy

- Antiemetics

  15-30 minutes prior to chemotherapy

  - metoclopramide 10mg oral or intravenous

  As take home medication on **day 1** only;

  - metoclopramide 10mg three times a day when required oral

- Gastric protection with a proton pump inhibitor or a H_2 antagonist may be considered in patients considered at high risk of GI ulceration or bleed.

Coding

- Procurement – X71.1
- Delivery – X72.2 / X72.4

References
1. Clinical Study Protocol. A prospective multicenter open label centrally allocated active controlled phase 2 study to evaluate the efficacy and safety of masitinib in combination with gemcitabine versus gemcitabine alone in advanced / metastatic epithelial ovarian cancer patients in second line being refractory to first line platinum treatment or in third line. EudraCT2013-000491-14 Ver 3

REGIMEN SUMMARY

Gemcitabine

Day 1, 8, 15

1. Metoclopramide 10mg oral or intravenous

2. Gemcitabine 1000mg/m^2 intravenous infusion in 250ml sodium chloride 0.9% over 30 minutes

Take Home Medicines (day 1 only)

3. Metoclopramide 10mg three times a day when required oral
   Administration Instructions
   Please supply 60 tablets or nearest original pack as appropriate

DOCUMENT CONTROL

Version	Date	Amendment	Written By	Approved By
1	Aug 2015	None	Dr Deborah Wright Pharmacist	Dr Harish Reddy Consultant Clinical 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 Hospital 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.