Lancashire & South Cumbria Cancer Network
Systemic Anticancer Treatment Protocol

Drug regimen
Cisplatin & Capecitabine (anal cancer)

Indications for use
Metastatic/recurrent/advanced inoperable squamous cell cancer of the anus

1st line use: contraindications to carboplatin & paclitaxel
2nd and subsequent line use: previous treatment with carboplatin & paclitaxel
Patient has received previous treatment with mitomycin C as part of concurrent chemoradiotherapy (and therefore not suitable for further treatment with mitomycin with MCX)
Fluoropyrimidine sensitive disease, (> 6 months since previous therapy)
No significant co-morbidities which outweigh the potential toxicities
Performance status 0 or 1 (PS 2 patients may be treated at consultants discretion)
Ability to comply with an oral chemotherapy regimen
HIV+ patients will be considered eligible if they are on Highly Active Anti-Retroviral Therapy (HAART) and have a CD4 count of ≥200/µl (HIV+ patients who are on HAART and have a CD4 count <200/µl are eligible if the plasma viral load is below the level of detection according to the local assay).

Regimen

DAY	DRUG	FLUID	TIME
1	20mmol potassium chloride + 10mmol magnesium sulphate	1 litre 0.9% sodium chloride	2 hours
1	Cisplatin 60mg/m^2	500ml 0.9% sodium chloride	1 hour
1	20mmol potassium chloride + 10mmol magnesium sulphate	1 litre 0.9% sodium chloride	2 hours
1-21	Capecitabine 625mg/m^2 orally twice daily		

Regimen to be repeated every 3 weeks for 4-8 cycles (at clinician's discretion)

Investigation prior to initiating treatment
Audiometry (at discretion of consultant)
Calculated Creatinine clearance (Cl_{Cr})
Biochemistry profile
Dihydropyrimidine dehydrogenase (DPD) deficiency can result in severe toxicity secondary to reduced fluorouracil metabolism (this can present as severe diarrhoea and/or severe stomatitis early in the first cycle). Patients require DPD testing prior to administration. Dose adjustments should be made in accordance with local DPD policy.

Cautions
History of cardiac disease
- History of severe and unexpected reactions to fluoropyrimidine therapy
- Moderate to severe renal impairment (creatinine clearance < 45mL/min- consider switching cisplatin to carboplatin AUC 5)
- Moderate to severe hepatic impairment
- Severe myelosuppression (> grade 3)
- Pregnancy/lactation
- Other significant co-morbidities that may prevent safe administration of chemotherapy e.g. pre-existing conditions pre-disposing to severe diarrhoea
- Patients taking nephrotoxic medication, such as NSAIDs, are at increased risk of additive toxicity with cisplatin

Consider capping doses at 2.2m2, doses above this at consultant discretion.

Additional medication:
This regimen is classified as highly emetogenic (>90% of patients).

Investigations and consultations prior to each cycle

FBC
Biochemical profile
Calculated Creatinine clearance

Consultation prior to each cycle

Acceptable limits for treatment to proceed (if outside these delay one week or contact consultant)

Delay treatment 1 week or until platelets ≥ 100 and neutrophils ≥ 1.5
Cl_{Cr} ≥ 55

If neutrophils 1.2-1.5 contact **consultant**

Side Effects

- Mucositis → Corsodyl / Difflam Mouth Wash
- Diarrhoea → Loperamide
- Skin rashes → plantar palmar syndrome
- Neutropenic sepsis
- Cisplatin: renal failure, high tone and hearing loss
- 5% - 10% incidence of precipitation of angina, chest pain must be taken seriously

Dose Modification Criteria
If calculated creatinine clearance 50 – 55 reduce cisplatin dose by 20%
If calculated creatinine clearance < 50 contact consultant
Reduce cisplatin and capecitabine doses by 25% following febrile neutropenia or more than 2 delays due to haematological toxicity

Specific Information on Administration
Capecitabine can be dissolved in 200ml of water for patients with swallowing difficulties or for administration via a feeding tube. Do not crush the tablets. Cordial can be added to the solution to make it more palatable.

Extravasation:
Cisplatin is a non-vesicant
Refer to network guidance for the prevention and management of extravasation

THIS PROTOCOL HAS BEEN DIRECTED BY DR WILLIAMSON, CLINICIAN FOR COLORECTAL CANCER

RESPONSIBILITY FOR THIS PROTOCOL LIES WITH THE HEAD OF SERVICE

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