Chemotherapy Protocol

HEAD AND NECK CANCER

METHOTREXATE

Regimen

- Head and Neck Cancer – Methotrexate

Indication

- Advanced head and neck cancer
- WHO Performance status 0, 1, 2

Toxicity

Drug	Adverse Effect
Methotrexate	Stomatitis, conjunctivitis, renal toxicity

The presence of a third fluid compartment e.g. ascities or renal failure may delay methotrexate clearance hence increase toxicity.

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

Monitoring

Regimen

- FBC, U&E's and LFT's prior to each cycle.

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 the following treatment criteria must be met on day 1 of treatment.

Criteria	Eligible Level
Neutrophil	equal to or more than $1x10^9$/L
Platelets	equal to or more than $100x10^9$/L

Consider blood transfusion if patient symptomatic of anaemia or has a haemoglobin of less than 9.5g/dL

If counts on day one are below these criteria for the neutrophils and/or platelets then delay treatment for seven days. Treatment should only be re-started when these levels are reached. Treatment may be resumed at the original dose or reduce the dose of methotrexate to 80% of the original dose depending on clinical circumstances. If a second episode of neutropenia and / or thrombocytopenia occurs or the time to reach the eligible level is longer than 7 days consider stopping or changing treatment.

Kidney Impairment

Drug	Creatinine Clearance (ml/min)	Dose (% of original dose)
Methotrexate	More than 80	100%
	60	65%
	45	50%
	Less than 30	CI

Liver Impairment

Drug	Bilirubin µmol/L		AST/ALT units	Dose (%of original dose)
Methotrexate	Less than 50	and	Less than 180	100%
	51-85	or	More than 180	75%
	More than 85			CI

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.

Regimen

14 day cycle for 6 cycles

Drug	Dose	Days	Administration
Methotrexate	100mg/m²	1	Intravenous bolus in 100ml sodium chloride 0.9% over 10 minutes

Dose Information

- Methotrexate will be dose banded as per the CSCCN agreed bands

Extravasation

- Methotrexate - inflammitant

Additional Therapy

- Antiemetics

  15-30 minutes prior to chemotherapy on days 1;

  - dexamethasone 4mg oral or equivalent intravenous dose
  - metoclopramide 10mg oral or intravenous

  As take home medication:

  - metoclopramide 10mg three times a day when required oral

- Folinic acid 15mg four times a day for 2 days oral starting 24 hours after methotrexate administration.

- Mouthwashes according to local or national policy on the treatment of mucositis.

- 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 - X70.1

- Delivery - Intravenous – X72.3

References

REGIMEN SUMMARY

Methotrexate

Day One

1. Dexamethasone 4mg oral or equivalent intravenous dose

2. Metoclopramide 10mg oral or intravenous

3. Methotrexate 100mg/m² intravenous bolus in 100ml sodium chloride 0.9% over 10 minutes.

Take Home Medicines

4. Metoclopramide 10mg three times a day oral when required oral

8. Folinic acid 15mg four times a day for 2 days oral starting 24 hours after methotrexate administration

Document Control

Version	Date	Amendment	Written By	Approved By
1	July 2015	None	Dr Debbie Wright Pharmacist	Dr K Bradley 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.