Chemotherapy Protocol

COLORECTAL CANCER

RALTITREXED

Regimen

- Colorectal Cancer – Raltitrexed

Indication

- Treatment of metastatic / advanced colorectal cancer where fluorouracil and / or capecitabine is contra-indicated due to cardiac adverse effects
- WHO Performance status 0, 1, 2
- Palliative intent

Toxicity

<table>
<thead>
<tr>
<th>Drug</th>
<th>Adverse Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raltitrexed</td>
<td>Diarrhoea, anorexia, raised transaminase levels</td>
</tr>
</tbody>
</table>

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 criteria must be met;

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Eligible Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neutrophil</td>
<td>equal to or more than 1.5x10^9/L</td>
</tr>
<tr>
<td>Platelets</td>
<td>equal to or more than 100x10^9/L</td>
</tr>
</tbody>
</table>
Consider blood transfusion if patient symptomatic of anaemia or has a haemoglobin of less than 8g/dL

If the neutrophils are less than 1.5x10^9/L and/or the platelets are less than 100x10^9/L then delay treatment for 7 days. If the counts recover at this time restart the raltitrexed at the original dose. If a 14 day delay is required to allow counts to recover or there are two separate delays of 7 days during treatment consider reducing the dose of raltitrexed to 80% of the original dose or stopping treatment.

**Kidney / Liver Impairment**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Hepatic</th>
<th>Renal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raltitrexed</td>
<td>If AST/ALT are less than 5xULN or bilirubin is less than 10xULN then treat at 100% dose.</td>
<td>CrCl is equal to or greater than 65ml/min then no reduction is necessary.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CrCl is between 55-65ml/min then administer 75% of the original dose 4 weekly.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CrCl is 25-54ml/min then administer 50% of the original dose 4 weekly.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>If the CrCl is less than 25ml/min then omit.</td>
</tr>
</tbody>
</table>

**Other Toxicities**

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. Dose limiting toxicities include diarrhoea, abdominal pain, emesis, stomatitis and palmer-plantar erythrodysasthesia among others.

**Regimen**

**21 day cycle for 8 cycles**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dose</th>
<th>Days</th>
<th>Route</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raltitrexed</td>
<td>3mg/m²</td>
<td>1</td>
<td>Intravenous infusion in 250ml sodium chloride 0.9% over 15 minutes</td>
</tr>
</tbody>
</table>

**Dose Information**

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

**Administration Information**

**Extravasation**

- Raltitrexed - inflammitant
Additional Therapy

- Antiemetics
  
  15-30 minutes prior to chemotherapy
  
  - metoclopramide 10mg oral or intravenous

  As take home medication;
  
  - metoclopramide 10mg three times a day when required oral

- Gastric protection with a proton pump inhibitor or a H₂ antagonist may be considered in patients considered at high risk of GI ulceration or bleed.

Coding

- Procurement – X70.4
- Delivery – X72.3

References

REGIMEN SUMMARY

Day One

1. Metoclopramide 10mg oral or intravenous

2. Raltitrexed 3mg/m² intravenous injection in 250ml sodium chloride 0.9% over 15 minutes

Take Home Medicines

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