Chemotherapy Protocol

PANCREATIC CANCER

GEMCITABINE

Regimen

- Pancreatic Cancer – Gemcitabine

Indication

- Adjuvant treatment of pancreatic cancer
- First line treatment of advanced pancreatic cancer
- WHO Performance status 0, 1, 2

Toxicity

<table>
<thead>
<tr>
<th>Drug</th>
<th>Adverse Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gemcitabine</td>
<td>Diarrhoea, constipation, rash, respiratory problems (pneumonitis), influenza like symptoms, radiosensitising, transient elevation of LFTs</td>
</tr>
</tbody>
</table>

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, 6, 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 $1.5 \times 10^9$/L
Platelets | equal to or more than $100 \times 10^9$/L

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

On the day of gemcitabine administration, if the neutrophils are $0.5-1 \times 10^9$/L and/or the platelets $50-100 \times 10^9$/L then administer 75% of the original dose. If the neutrophils are less than $0.5 \times 10^9$/L and the platelets are less than $50 \times 10^9$/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 $0.5-1 \times 10^9$/L or platelet count between $50-100 \times 10^9$/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**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Bilirubin (µmol/L)</th>
<th>AST/ALT</th>
<th>Dose (% of original dose)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gemcitabine</td>
<td>Consider dose reductions especially where the bilirubin is raised</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Renal Impairment**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Creatinine Clearance (ml/min)</th>
<th>Dose (% of original dose)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gemcitabine</td>
<td>Consider dose adjustments when the CrCl is less than 30ml/min</td>
<td></td>
</tr>
</tbody>
</table>

**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

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dose</th>
<th>Days</th>
<th>Administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gemcitabine</td>
<td>1000mg/m²</td>
<td>1, 8, 15</td>
<td>Intravenous infusion in 250ml sodium chloride 0.9% over 30 minutes</td>
</tr>
</tbody>
</table>

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 H₂ 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

REGIMEN SUMMARY

Gemcitabine

Day One

1. Metoclopramide 10mg oral or intravenous

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

Day Eight

3. Metoclopramide 10mg oral or intravenous

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

Day Fifteen

5. Metoclopramide 10mg oral or intravenous

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

Take Home Medicines (day one only)

7 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.