Chemotherapy Protocol

BREAST CANCER

PACLITAXEL ALBUMIN BOUND

Regimen

- Breast Cancer – Paclitaxel Albumin Bound

Indication

- Paclitaxel albumin bound can be prescribed where;
  - there is a confirmed histological or cytological breast cancer
  - there is a confirmed severe paclitaxel hypersensitivity which precludes further exposure to paclitaxel (patients who have had a severe hypersensitivity reaction to docetaxel should have been switched to a trial of paclitaxel)
  - the patient is being switched to paclitaxel albumin bound from either paclitaxel or docetaxel to reduce the toxicity of treatment and / or to reduce the number of admissions required for administration of treatment during the COVID-19 pandemic

- Paclitaxel albumin bound will be used as a single agent or in combination for neo-adjuvant, adjuvant or metastatic disease (note that neo-adjuvant and adjuvant treatment are unlicensed)

- WHO Performance status 0, 1

Toxicity

<table>
<thead>
<tr>
<th>Drug</th>
<th>Adverse Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paclitaxel Albumin Bound</td>
<td>Neuropathy, hypersensitivity, arthralgia, back pain, alopecia, rash</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 today one of the 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 cycle one 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 $1.5 \times 10^9$/L</td>
</tr>
<tr>
<td>Platelets</td>
<td>equal to or more than $100 \times 10^9$/L</td>
</tr>
</tbody>
</table>

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

Treatment should be delayed if the neutrophil count is less than $1 \times 10^9$/L and / or if the platelets are less than $100 \times 10^9$/L. If counts recover at this point treatment may continue at the same dose for a NCI-CTC grade 1 or 2 toxicity. For a NCI-CTC grade 3 or above toxicity reduce the dose to 220mg/m$^2$. If a second recurrence of a NCI-CTC grade 3 toxicity resume treatment on recovery using a dose of 180mg/m$^2$.

The treatment indication should be considered when deciding on dose reductions.

**Hepatic Impairment**

<table>
<thead>
<tr>
<th>Grade</th>
<th>ALT</th>
<th>Bilirubin</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moderate</td>
<td>less than 10xULN</td>
<td>1.25-2xULN</td>
<td>200mg/m$^2$</td>
</tr>
<tr>
<td>Severe</td>
<td>less than 10xULN</td>
<td>2.01-5xULN</td>
<td>130mg/m$^2$</td>
</tr>
<tr>
<td>Severe</td>
<td>greater than 10xULN</td>
<td>Greater than 5xULN</td>
<td>Do not use</td>
</tr>
</tbody>
</table>

In severe impairment if the initial dose of 130mg/m$^2$ is tolerated consider increasing to 200mg/m$^2$.

**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>Paclitaxel albumin bound</td>
<td>No information available</td>
<td></td>
</tr>
</tbody>
</table>

**Other**

**Sensory Neuropathy**

For those who experience a NCI-CTC grade 3 or above neuropathy allow symptoms to settle to NCI-CTC grade 1 or 2 and resume treatment at a dose of 220mg/m$^2$. Following a recurrence reduce the dose to 180mg/m$^2$.

For those who experience a NCI-CTC grade 2 neuropathy reduce the dose to 220mg/m$^2$. If the neuropathy recurs at NCI-CTC grade 2 this should be reduced to 180mg/m$^2$. 
Regimen

21 day cycle – 6 cycles will be set in ARIA (the number of cycles may vary with indication)

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dose</th>
<th>Days</th>
<th>Administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paclitaxel albumin bound</td>
<td>260mg/m²</td>
<td>1</td>
<td>Intravenous infusion over 30 minutes</td>
</tr>
</tbody>
</table>

Dose Information

- Paclitaxel albumin bound will be dose banded in accordance with the national dose bands

Administration Information

Extravasation

- Paclitaxel albumin bound - vesicant

Other

- The use of medical devices containing silicone oil as a lubricant (i.e. syringes and IV bags) to reconstitute and administer paclitaxel albumin bound may result in the formation of proteinaceous strands. Administer using an infusion set incorporating a 15 µm filter to avoid administration of these strands. Use of a 15 µm filter removes strands and does not change the physical or chemical properties of the reconstituted product. Use of filters with a pore size less than 15 µm may result in blockage of the filter.

Additional Therapy

- Antiemetics

  No antiemetics are required prior to treatment

  As take home medication on cycle 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.

References

REGIMEN SUMMARY

Paclitaxel Albumin Bound (Abraxane)

Cycle 1-day 1

1. Paclitaxel albumin bound 260mg/m² intravenous infusion over 30 minutes
   Administration Instructions
   The use of medical devices containing silicone oil as a lubricant (i.e. syringes and IV bags) to reconstitute and administer paclitaxel albumin bound may result in the formation of proteinaceous strands. Administer using an infusion set incorporating a 15 µm filter to avoid administration of these strands. Use of a 15 µm filter removes strands and does not change the physical or chemical properties of the reconstituted product. Use of filters with a pore size less than 15 µm may result in blockage of the filter.

Take Home Medicines

2. Metoclopramide 10mg three times a day when required oral
   Administration Instructions
   Please supply 30 tablets or one original pack as appropriate

Cycle 2 onwards-day 1

3. Paclitaxel albumin bound 260mg/m² intravenous infusion over 30 minutes
   Administration Instructions
   The use of medical devices containing silicone oil as a lubricant (i.e. syringes and IV bags) to reconstitute and administer paclitaxel albumin bound may result in the formation of proteinaceous strands. Administer using an infusion set incorporating a 15 µm filter to avoid administration of these strands. Use of a 15 µm filter removes strands and does not change the physical or chemical properties of the reconstituted product. Use of filters with a pore size less than 15 µm may result in blockage of the filter.
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.