Great Western Hospitals NHS Foundation Trust

Patient agreement for unlicensed Rituximab Rapid Rate Infusion

Rituximab is a drug used to treat a number of haematological conditions including Non-Hodgkin Lymphoma (NHL) and Chronic Lymphocytic Leukaemia (CLL). It belongs to a class of drugs known as monoclonal antibodies. It attaches specifically to a protein that is found on the surface of white blood cells, enabling your immune system to target and kills these cells.

Clinical experience suggests that a rapid (1.5hours) rituximab infusion scheduled, in combination with paracetamol, an antihistamine and steroids before each infusion, is well tolerated and safe, when administered from the third infusion onwards.

Infusion-related reactions can occur when rituximab is being given. These include headache, rash, flushing, chest tightness, short of breath and chills and are particularly likely to occur during your first rituximab infusion. These reactions are often mild, but they can be severe.

Eligible criteria for Rapid infusion Rate
Patients receiving subsequent rituximab infusion who have received and tolerated the first full dose (375mg/m2 for NHL and 500mg/m2 for CLL) rituximab infusion at standard rate without a grade 2 or more infusion-related adverse reactions when rituximab is prescribed in the following settings:

- Rituximab combined with steroid and non-steroid containing chemotherapy (excluding CLL patients on FCR chemotherapy).
- In NHL, rituximab monotherapy including as 2 or 3 monthly maintenance in patients who have received previous rituximab infusion as part of the combination induction therapy.
- For CLL patients, they must have previously received the full 500mg/m2 without ≥ 2 IRR, rapid infusion therefore would usually start from cycle 3 on-ward.

First Infusion
The initial infusion is 50mg/h for the first 30 minutes.
Thereafter, if no reaction, the rate can be escalated in 50mg/h increments every 30 minutes to a maximum rate of 400mg/h.

Subsequent infusions: After the first infusion, subsequent infusions can be given at either the licensed rate or rapid rate (for those eligible to receive rapid infusion).

Subsequent infusions licensed rate
Subsequent doses of rituximab can be infused at an initial rate of 100 mg/h, and increased by 100 mg/h increments at 30 minute intervals, to a maximum of 400 mg/h.

Subsequent infusions Rapid rate (for those eligible to receive rapid infusion)
Cycle 2 and subsequent cycles (cycle 3 onward in case of CLL)
Rituximab prepared in 500 ml sodium chloride 0.9%.
Infuse 100 ml of the rituximab infusion (20% of the dose) over 30 minutes.
Then infuse the remaining 400 ml (80% of the dose) over 60 minutes (total infusion time 90 minutes).

Patient should receive pre-medications with the first rapid rate infusion:

- Paracetamol 1000mg PO
- Chlorphenamine 10mg IV
- Hydrocortisone 100mg IV bolus (or steroid component of chemotherapy regimen)

Checklist for Rituximab rapid infusion rate

- Infusion related reaction to first cycle of rituximab:
  None Mild Severe

If patient had no or only mild reaction to rituximab during the first cycle the 2nd and subsequent rituximab infusions can be administered following the rapid infusion protocol.

Those patients who had a major reaction to first cycle rituximab should have second and subsequent cycles administered following the SPC - **Subsequent infusions licensed rate.**

Patient has been informed rapid infusion rituximab is unlicensed but is happy to participate.

Patient Signature _____

Date _____ Staff Signature _____ Date _____