Great Western Hospitals NHS Foundation Trust

Patient agreement for unlicensed Daratumumab Rapid Rate Infusion

Daratumumab is a drug used to treat multiple myeloma and belongs to a class of drugs known as monoclonal antibodies. It attaches specifically to a protein that is found on the surface of myeloma cells, enabling your immune system to target and kills these cells.

Data suggests that a rapid (1.5hours) daratumumab 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 daratumumab is being given. These include shortness of breath, blocked sinuses, coughing, raised blood pressure and chills and are particularly likely to occur during your first daratumumab infusion. These reactions are often mild, but they can be severe.

If you have Chronic obstructive pulmonary disease (COPD), asthma or uncontrolled hypertension, you may be at an increased risk of experiencing daratumumab reaction symptoms. Please let your chemotherapy nurse and doctor know as you may not be able to have the daratumumab rapid rate.

Rapid infusion Rate

CYCLE 2 and subsequent cycle doses for those patients eligible to receive rapid rate:
Daratumumab prepared in 500 ml sodium chloride 0.9%.
Infuse 100 ml of the daratumumab 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
- Montelukast 10mg PO (first rapid rate infusion only)
- Dexamethasone 20mg IV bolus or PO (give IV prior to the first rapid rate infusion)

Checklist for Daratumumab rapid infusion rate

- Past Medical History (including exclusion criteria checked):

- Infusion related reaction to first cycle of Daratumumab was less than or equal to Grade 1:
  Yes or No

Patient must have received and tolerated the previous 500mL daratumumab infusion at the standard manufacturer licensed rate without ≥ Grade 1 infusion-related reactions. Daratumumab can be administered following the rapid infusion protocol from cycle 2 onwards as per the TVSCN protocol.

Those patients who had IRR>1 should continue to receive daratumumab at the standard infusion rate as per TVSCN protocol.

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

Patient Signature _____

Date _____ Staff Signature _____ Date _____