

DRUG REGIMEN

Rituximab + Gemcitabine

Indication for use

High grade B-cell Lymphoma

Regimen

Cycle 1

| | | | | |
|------------------|----------------|-----------------------|----|--|
| Day 1, 8 & 15 | Paracetamol | 1000mg | PO | 1 hour prior to Rituximab |
| | Chlorphenamine | 10mg | IV | 30min prior to Rituximab |
| | Rituximab* | 375mg/m ² | IV | in 500ml Sodium Chloride 0.9% (infuse as per local protocol) |
| | Gemcitabine | 1000mg/m ² | IV | in 250ml Sodium Chloride 0.9% over 30mins |
| Day 22 | Paracetamol | 1000mg | PO | 1 hour prior to Rituximab |
| | Chlorphenamine | 10mg | IV | 30min prior to Rituximab |
| | Rituximab* | 375mg/m ² | IV | in 500ml Sodium Chloride 0.9% (infuse as per local protocol) |

Cycle 2 onwards

| | | | | |
|------------|----------------|-----------------------|----|--|
| Day 1 | Paracetamol | 1000mg | PO | 1 hour prior to Rituximab |
| | Chlorphenamine | 10mg | IV | 30min prior to Rituximab |
| | Rituximab* | 375mg/m ² | IV | in 500ml Sodium Chloride 0.9% (infuse as per local protocol) |
| | Gemcitabine | 1000mg/m ² | IV | in 250ml Sodium Chloride 0.9% over 30mins |
| Day 8 & 15 | Gemcitabine | 1000mg/m ² | IV | in 250ml Sodium Chloride 0.9% over 30mins |

Repeat every 28 days for 4 - 6cycles

*Refer to local Trust Rituximab Infusion Policy

| | |
|---------------------------------|--|
| Prophylaxis for acute emesis: | Give Metoclopramide 20mg IV pre med |
| Prophylaxis for delayed emesis: | Metoclopramide 10mg TDS PRN |
| Other medications: | Allopurinol 300mg od for 5 days with cycle 1 |

Investigation prior to initiating treatment

Prior to a course:

- Patient should have adequate bone marrow reserve before commencing treatment, i.e neuts >1.0, platelets >50 unless due to marrow infiltration, splenomegaly.- *if not discuss with consultant*
- Use Gemcitabine with caution if LFTs abnormal – *discuss with consultant & see dose modification*
- Written consent for course

Cautions

Allergic reaction: see Rituximab infusion protocol

If the lymphocyte count is > 20 x 10⁹/L the patient is at greater risk of cytokine-release Syndrome: see Rituximab infusion protocol

Investigations and consultations prior to each cycle

Prior to each cycle

- Medical review of **fitness for chemotherapy** – exclude active infection, major changes in organ function
- Check **FBC** on day 1– neuts must be > 1.0 and platelets >50 prior to each cycle. *See dose modifications*
- Check **U&Es, creat, LFTs**– *see dose modifications*

Acceptable levels for treatment to proceed (if outside these levels defer one week or contact consultant)

Side Effects

Gemcitabine Toxicities

Neutropenic sepsis & thrombocytopenia
Somnolence & fatigue

Alopecia

Rash & pruritus

Haemolytic-uraemic syndrome

Nausea & vomiting (moderate)

Amenorrhoea & infertility (offer semen cryopreservation)

Liver dysfunction

Dyspnoea – pneumonitis

Dose Modification Criteria

Dose modification for haematological toxicity and infection

| | |
|--|---|
| If day 28 neutrophils <1.0 or platelets <50 | Delay until these levels reached and proceed with GCSF prophylaxis starting day 9 or 25% dose reduction |
| If day 28 counts remain low despite 50% dose reduction and/or GCSF | <i>Discuss with consultant</i> – further treatment may be inappropriate |
| If there is neutropenic sepsis | <i>Discuss with consultant</i> - consider using GCSF prophylaxis starting day 9 or further treatment may be inappropriate |
| If there is neutropenic sepsis despite GCSF | Stop treatment |

Dose modification for abnormal liver function

If **bilirubin >27µmol/L** there is an increased risk of **hepatic toxicity** due to gemcitabine. Consider starting at a reduce dose of gemcitabine 800mg/m² and escalating according to tolerance

Specific Information on Administration

Follow the local Rituximab infusion protocol

THIS PROTOCOL HAS BEEN DIRECTED BY DR KANYIKE – CONSULTANT HAEMATOLOGIST

RESPONSIBILITY FOR THIS PROTOCOL LIES WITH THE HEAD OF SERVICE

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