North West Coast
Strategic Clinical Networks

Chemotherapy protocol

Drug Regimen
Trastuzumab

Indications for use
Early or metastatic breast cancer in patients whose tumours over express Her-2 receptors at 3+ level

Concurrent regimens
When used in combination with a chemotherapeutic agent reference should be made to that respective protocol and the two protocols (trastuzumab and chemotherapeutic) used in tandem.

3 weekly trastuzumab may be given concurrently with:
Paclitaxel, docetaxel, vinorelbine, liposomal doxorubicin, capecitabine, carboplatin

Regimen

DAY	DRUG	FLUID	TIME
1	Trastuzumab 8mg/kg	250ml N/saline	IV over 90 mins
21	Trastuzumab 6mg/kg	250ml N/saline	IV over 30 mins

Then repeat Day 21 every 3 weeks (total 18 doses for adjuvant therapy)

If trastuzumab is to be given concurrently with another chemotherapeutic agent, the trastuzumab should be given first. Patients should be observed for 90 minutes after the first dose of trastuzumab.

If the treatment is tolerated there should be a minimum duration of 8 weeks before response assessment. In case of response, treatment can be continued until disease progression.

Investigations prior to initiating treatment
Her-2 testing is **mandatory**
ECG
MUGA scan/ Echocardiogram
FBC, U&Es, LFTs especially when given in combination with chemotherapy

Requirements

- Her2 Over expression at 3+ level as determined by IHC
- Life expectancy greater than 6/12
- WHO performance status ≥2
- LVEF ≥50%

Contra-indication
Patients experiencing dyspnoea at rest due to either co-morbidities or complications of advanced malignant disease should *not* receive trastuzumab.

Cautions

- Uncontrolled hypertension or angina
- Known allergies to animal proteins.
- Symptomatic heart failure
- Previous exposure to anthracycline chemotherapy

Investigations and consultations prior to each cycle
MUGA Scan every 4 months (or if patient has asymptomatic cardiac dysfunction every 6 or 8 weeks) in the adjuvant setting or every 6 months in the metastatic setting

As a single agent in the adjuvant setting FBC every 3 months unless clinical symptoms dictate otherwise

As a single agent in the metastatic setting FBC, U&Es, LFTs and bone profile should be checked every 12 weeks if clinically stable unless instructed otherwise by consultant

If neutrophils < 1.0 or platelets <80 contact consultant before administration. If counts are chronically low then refer results to consultant for information only after administration.

Side Effects
Infusion related:

Mild – Chills and rigor, tumour site pain, nausea and vomiting, asthenia, headache, cardiotoxicity.
Severe – Dyspnoea, hypotension, urticaria/angioedema, anaphylaxis

Specific Information on Administration
Pre-med: Paracetamol 1 gm 30-60 minutes before treatment, and regularly for 24 hours after treatment.

Treatment of side effects:

Mild – Stop infusion. Give 10 mg IV Piriton and 100 mg IV Hydrocortisone. Re start infusion slowly after 30 minutes. If further problems discontinue infusion and seek senior advice.

Severe – Stop infusion. Give 100 mg Hydrocortisone and 10 mg Piriton stat. Get HELP. May need further resuscitation. Patient to be admitted. If severe liver capsule or bone pain occurs give Pethidine 25 – 50 mg IV.

Missed doses:

If the patient has missed a dose by more than one week, a re-loading dose of 8mg/kg should be administered over approximately 90 minutes as soon as possible. Subsequent maintenance doses of 6mg/kg should be administered 21 days later

THIS PROTOCOL HAS BEEN DIRECTED BY DR HOGG, DESIGNATED LEAD CLINICIAN FOR BREAST CANCER

RESPONSIBILITY FOR THIS PROTOCOL LIES WITH THE HEAD OF SERVICE

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