| Protocol title | Adriamycin+Cyclophosphamide |
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| Administration | Intravenous |
| Schedule | 2 weekly |
| Antiemetic risk +  Antiallergic medications +  Premedications + Post chemotherapy medications | Intravenous- High emetic risk |
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| Chemotherapy dose and method of administration | Injection Adriamycin 60 mg /m2 over in 250 ml NS IV over 30 minutes on D1  Injection Cyclophosphamide 600 g/m2 IV in 100 ml NS over 30 minutes on D1  ***Dose levels for Adriamycin***  Dose level 0- 60 mg/m2  Dose level 1- 55 mg/m2  Dose level 2- 37 mg/m2  ***Dose levels for Cyclophosphamide***  Dose level 0- 600 mg/m2  Dose level 1- 500 mg/m2  Dose level 2- 400 mg/m2 |
| Number of days of chemotherapy in each cycle | 1 |
| Number of cycles | 4 |
| FN risk | >20% |
| Antithrombotic prophylaxis | To follow the Khorana score. |
| Special instruction to Nurse | 1. Orders related checks    1. To check whether the orders for chemotherapy are signed manually or by using electronic approval by licensed independent practitioners who are determined to be qualified by the health care setting.    2. Verbal orders are not allowed from medical practitioners except to hold or stop chemotherapy administration.    3. **Check Consent**    4. To check new orders or changes to orders, including changes to regimens, for example, dose adjustments communicated directly to patients, are documented in the medical record.    5. Check patient’s name and a second patient identifier like a phone number    6. The date of order is written (Orders are valid for only 3 working days)    7. Regimen or protocol name and number, Cycle number and day, when applicable    8. All medications within the order set are listed by using full generic names    9. Drug dose is written following standards for abbreviations, trailing zeros, and leading zeros.    10. Route of administration 2. Before preparation, a second person—a practitioner or other personnel approved by the health care setting to prepare or administer chemotherapy— independently verifies    1. Two patient identifiers.    2. Drug name.    3. Drug dose.    4. Route of administration.    5. Rate of administration    6. The calculation for dosing, including the variables used in this calculation.    7. Treatment cycle and day of the cycle 3. Upon preparation, a second person approved by the health care setting to prepare parenteral chemotherapy verifies:    1. The drug vial(s).    2. Concentration.    3. Drug volume or weight.    4. Diluent type and volume    5. Administration fluid type, volume, and tubing. 4. Chemotherapy drugs are labeled immediately upon preparation, and labels include the following 10 elements at a minimum:    1. Patient’s name.    2. A second patient identifier.    3. Full generic drug name.    4. Drug dose.    5. Drug administration route.    6. The total volume required to administer the drug.    7. Date the medication is to be administered.    8. Expiration dates and/or times.    9. Sequencing of drug administration, when applicable, and the total number of products to be given when medication is provided in divided doses—each product should be labeled with the total number of products to be administered and the sequence of the individual product within that total grouping, for example, one of five, two of two, etc.    10. A warning or precautionary label or sticker, as applicable, to storage and handling; may be included within the label or on an auxiliary label 5. Administration    1. Before initiation of each chemotherapy administration cycle, the practitioner who is administering the chemotherapy confirms the treatment with the patient, including, at a minimum, the name of the drug, infusion time, route of administration, and infusion-related symptoms to report—for example, but not limited to, hypersensitivity symptoms or pain during infusion.    2. At least two individuals, in the presence of the patient, verify the patient identification by using at least two identifiers.    3. Check vitals before starting. They need to be within the institutes/centers approved normal limits    4. Use a new IV cannula or Chemo port and needs to be inserted at a sight with limited movements and not over a joint    5. Check for backflow prior to giving chemotherapy    6. In case of extravasation→ Follow the institutes/centers approved extravasation algorithm    7. In case of hypersensitivity→ Follow the institutes/centers approved extravasation algorithm    8. In case of breathlessness or chest pain or syncope or bradycardia → Follow an emergency cardiac algorithm |
| Special instruction to Patients | 1. Encourage oral hydration 2. In case of any emergency - Please visit the outpatient/ causality of …. hospital 3. Please respond to daily SMS sent for enquiring about your health 4. In case of fever or more than 2 loose motions/vomiting or giddiness or weakness or any other troublesome symptom. Please visit the outpatient/ causality of …. hospital 5. Any change in appointment or rescheduling can be discussed on this ……………………..number 6. Please avoid any social visits or public places without discussing with your oncologists 7. Prefer homemade food and or food prepared in hygienic conditions 8. In addition please check the patient information booklet available with the medicines for detailed instructions on do and don'ts |
| Special instruction to Patients- Protocol specific | 1. To report incase of Burning sensation or skin discoloration at the injection site 2. Red Colour urination for 1-2 days upto 2 days after chemotherapy 3. To report in case of fever /Oral ulcers /Vomiting /Loose stools /Fatigue |
| Stockists instructions | Injection Adriamycin 10 mg/5 ml vial as solution  Injection Adriamycin 20 mg/10 ml vial as solution  Injection Adriamycin 50 mg/25 ml vial as solution  Injection Adriamycin 150 mg/75 ml vial as solution  Injection Adriamycin 200 mg/100 ml vial as solution  Injection Cyclophosphamide 500 mg lyophilized powder in vial  Injection Cyclophosphamide 1 g lyophilized powder in vial  Injection Cyclophosphamide 2 g lyophilized powder in vial |
| Next visit instructions | CBC ,RFT,LFT,S.Electrolytes,Mg ,RBS |
| Drug interactions | DOXORUBICIN  -Strong CYP3A Inhibitors-itraconazole, ketoconazole, posaconazole, voriconazole, clarithromycin, indinavir, lopinavir, nelfinavir and ritonavir  -Strong CYP3A Inducers-rifampicin  CYCLOPHOSPHAMIDE  Protease inhibitors |
| New cycle planning minimal requirements | Haemoglobin level >= 8 g/dl  Absolute Neutrophil Count>=1000/mm3  Platelet count >=75,000/ mm3  GFR >= 40 ml/min  All adverse events resolved to baseline or grade 1 (except fatigue or alopecia) |
| Dose modifications for adverse events | 1. Blood bilirubin increased 2. Grade 2 → reduce Adriamycin dose by 1 level 3. Grade 3 → reduce Adriamycin dose by 1 level 4. Grade 4 → discontinue Adriamycin 5. Febrile neutropenia 6. Grade 3/ 4 → reduce Adriamycin and Cyclophosphamide dose by 1 level |
| Special tests after a few cycles if any | - |
| Adverse events | Peripheral Neuropathy  Constipation  Bowel obstruction  Paralytic Ileus  Fatigue  Transaminitis  Pyrexia  Alopecia  Nausea/Vomiting  Stomatitis  Febrile Neutropenia  Cardiomyopathy  Second Malignancy  Skin and nail hyperpigmentation  Oncolysis  Rash  Itching  Photosensitivity  Urticaria  Palmar plantar erythrodysesthesia  Hemorrhagic cystitis |
| Risk of death | <1% |
| Comment | - |
| Reference | FDA drug label |