

Chemotherapy Protocol

ACUTE MYELOID LEUKAEMIA

CYTARABINE SC

Regimen

- Acute Myeloid Leukaemia – Cytarabine SC

Indication

- Acute myeloid leukaemia in those 60 years of age and over and / or not fit enough for intensive therapy
- MDS patients with intermediate, high risk or very high risk disease as defined by the International Prognostic Score System (IPSS-R).
- Leukemia that has relapsed post transplant

Toxicity

Drug	Adverse Effect
Cytarabine	Nausea, vomiting, diarrhoea, fever, rash, anorexia, oral and anal inflammation or ulceration, and hepatic dysfunction

The adverse effects listed are not exhaustive. Please refer to the relevant Summary of Product Characteristics for full details.

Monitoring

Drugs

- FBC, U&Es and LFTs prior to day 1 of the cycle

Dose Modifications

The dose modifications listed are for haematological, liver and renal function and drug specific toxicities only. Dose adjustments may be necessary for other toxicities as well.

In principle all dose reductions due to adverse drug reactions should not be re-escalated in subsequent cycles without consultant approval. It is also a general rule for chemotherapy that if a third dose reduction is necessary treatment should be stopped.

Haematological

Consider blood transfusion or erythropoietin if the patient is symptomatic of anaemia or has a haemoglobin of less than 8g/dL (80g/L).

Hepatic Impairment

Drug	Bilirubin μmol/L		AST/ALT units/L	Dose (% of original dose)
Cytarabine	Greater than 34		N/A	50% Escalate doses in subsequent cycles in the absence of toxicity

Renal Impairment

Drug	Creatinine Clearance (ml/min)	Dose (% of original dose)
Cytarabine		No dose modification required

Other

Dose reductions or interruptions in therapy are not necessary for those toxicities that are considered unlikely to be serious or life threatening. For example, alopecia, altered taste or nail changes.

For all other non-haematological NCI-CTC grade 3 and above toxicities delay treatment until the adverse effect has resolved to NCI-CTC grade 1 or below. The dose of the causative agent may then be reduced or discontinued at the discretion of the consultant.

Regimen

28-42 day cycle for at least 4 cycles (28 day cycle for 4 cycles will be set in ARIA)

Drug	Dose	Days	Administration
Cytarabine	20mg twice a day	1 – 10 (inclusive)	Subcutaneous injection

Administration Information

- Administer into the thigh or abdomen. Rotate the injection sites.

Additional Therapy

- Allopurinol 300mg once a day cycle one oral. This may be continued on subsequent cycles depending on response and counts
- Antiemetics
 - metoclopramide 10mg three times a day if required

Additional Information

- Subcutaneous cytarabine maybe administered in the out-patient setting providing 12 hourly administration can be arranged. For patients to receive this care in the community there must be clear arrangements for medical authorisation, support, problem-solving and emergency action between community services and the referring hospital.

- Cycles should ideally begin on a Monday, Tuesday or Wednesday so that only one weekend is included in each 10 day cycle

Coding

- Procurement – X70.1
- Delivery – X72.2

References

1. Thomas XG, Dmoszynska A, Wierzbowska A et al. Results from a randomised phase III trial of decitabine versus supportive care or low dose cytarabine for the treatment of older patients with newly diagnosed AML. J Clin Oncol 2011; 29 (15): 6504

REGIMEN SUMMARY

Cytarabine SC

Cycle 1, 2, 3, 4

Day 1-10 inclusive

1. Warning – Cytarabine is TWICE a day

Administration Instructions

The daily doses of cytarabine should be given 12 hours apart

2. Cytarabine 20mg twice a day subcutaneous bolus

Administration Instructions

Administer into the thigh or abdomen. Rotate injection sites.

Ensure adequate provision is in place to allow administration in the community. Pharmacy if this is to be given in the community please label accordingly.

If this is being given in an out or in-patient setting please record the administration in the patients journal on ARIA. There will be no means of electronically administering the agent on ARIA as it has been set up as a take home medicine.

3. Metoclopramide 10mg three times a day when required for the relief of nausea

Administration Instructions

Please supply 28 tablets or nearest original pack size.

3. Allopurinol 300mg once a day oral

Administration Instructions

Please review the need for allopurinol at each cycle. Match the number of tablets required to the length of the cycle.

DOCUMENT CONTROL

Version	Date	Amendment	Written By	Approved By
1	March 2017	New protocol	Lucy Shade Pharmacist	Dr Deborah Richardson Consultant Haematologist

This chemotherapy protocol has been developed as part of the chemotherapy electronic prescribing project. This was and remains a collaborative project that originated from the former CSCCN. These documents have been approved on behalf of the following Trusts;

Hampshire Hospitals NHS Foundation Trust
NHS Isle of Wight
Portsmouth Hospitals NHS Trust
Salisbury Hospitals NHS Foundation Trust
University Hospital Southampton NHS Foundation Trust
Western Sussex Hospitals NHS Foundation Trust

All actions have been taken to ensure these protocols are correct. However, no responsibility can be taken for errors that occur as a result of following these guidelines.