

Systemic Anti-Cancer Therapy Protocol**Low Dose Subcutaneous Cytarabine 5 days
in Langerhans Cell Histiocytosis (LCH)****Protocol Reference: MPHACYTMIS
(Version No: 1.0)****Approved for use in:**

Refractory Langerhan's Cell Histiocytosis when recommended by specialist.

Dosage:

Drug	Dosage	Route	Frequency
Cytarabine	100mg/m ²	SC	Daily on days 1-5

Cycle frequency:

Every 28 days for up to 12 cycles

Emetogenic risk:

Low risk

Supportive treatment:

Metoclopramide 10mg when required up to three times a day

Co-trimoxazole 960mg three times per week

Aciclovir 400mg twice a day

*Consider antifungal prophylaxis, anti-uremic therapy, mouthcare.***Renal and Hepatic Dosing:**

Dose Modifications	
Renal	No dose modifications are necessary
Hepatic	No dose modifications are necessary

Treatment Schedule:

Day	Drug	Dosage	Route	Administration
1-5	Cytarabine	100mg/m ² once a day	SC injection	Inject into the upper arm, thigh or abdomen. Injection sites should be rotated. New injections should be given at least 2.5cm from the previous site and never into tender, bruised or hardened areas

Drug Interactions:

- Cardiac glycosides – gastro-intestinal absorption of oral digoxin tablets may be substantially reduced in patients receiving combination chemotherapy regimens (including regimens containing cytarabine), possibly as a result of temporary damage to intestinal mucosa caused by the cytotoxic agents.
- Seek advice from pharmacy regarding any herbal or OTC medications.

Dose Modifications and Toxicity Management:**Haematological / Non-haematological toxicities:**

<i>Dose Modifications</i>	
Haematological	Generally ensure neutrophils and platelets have recovered prior to each cycle. Refer to consultant if neutrophils <1.0 or platelets <100.
Elderly population	No data is available to suggest that a change in dose is necessary in the elderly population. However, the elderly patient is more susceptible to toxic reactions and therefore particular attention should be paid to drug-induced leukopenia, thrombocytopenia and anaemia.

Investigations and treatment plan:

	Before Treatment	Prior to each cycle	Ongoing
Informed Consent	X		
Clinical Assessment	X	X	
SACT Assessment	X	X	
Observations (Blood pressure/ Pulse/ Temperature/ Respiratory rate)	X	X	
FBC	X	X	
U&Es, LFT, bone profile, uric acid	X	X	
Subcutaneous administration training	X		
Bone Marrow	X		If clinically appropriate
Virology (Hepatitis B/C serology, HIV, COVID-19 screen)	X		
PS recorded	X	X	Before treatment and prior to every cycle
Pregnancy test	X		As appropriate
Discuss infertility risk and possible preservation before treatment	x		
Height	X		
Weight	X	X	

Counselling points:

- Patients will be trained to self-administer Cytarabine when they start treatment. Clinical Nurse Specialists are responsible for providing this training.
- Syringes should be kept at room temperature. An appropriate sharps bin should be given to the patient for disposal of used syringes. The bin should be returned to the haematology unit once full and a new one supplied
- Contraceptive advice – males and females of childbearing potential must use effective contraceptive measures during and for up to 6 months following treatment.
- Cytarabine is contraindicated during breast-feeding.
- No known effect of cytarabine on the ability to drive or operate heavy machinery, but patients should be advised to avoid such tasks if they become in any way affected.

Main Toxicities:

Undesirable effects from cytarabine are dose-dependent.

- Myelosuppression (anaemia, leukopenia, thrombocytopenia)
- Immunosuppression
- Nausea and vomiting
- Diarrhoea
- Oral ulceration
- Fatigue
- Increased liver enzyme levels (reversible)
- Injection site reactions
- Less common – maculopapular rash, conjunctivitis and malaise

Refer to SPC for further information

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References:

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2. Girschikofsky et al. Management of adult patients with Langerhans cell histiocytosis: recommendations from an expert panel on behalf of Euro-Histio-NetOrphanet Journal of Rare Diseases 2013, 8:72. Available at www.ojrd.com/content/8/1/72 (Accessed 22/7/2020)
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