Chemotherapy Protocol

COLORECTAL CANCER

FLUOROURACIL-RADIOTHERAPY

Regimen

- Colorectal Cancer– Fluorouracil with concurrent radiotherapy

Indication

- Neoadjuvant treatment of rectal cancer.

Toxicity

Drug	Adverse Effect
Fluorouracil	Palmar-plantar erythrodysesthesia, diarrhoea, mucositis, chest pain, nausea, vomiting, stomatitis

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

Monitoring

Drugs

- FBC, LFT's and U&E's prior to day one of treatment. FBC, U&E and LFTs thereafter should be taken once a week at the point of pump change but treatment should not be delayed waiting for the results.

- Patients with complete or partial dihydropyrimidine dehydrogenase (DPD) deficiency are at increased risk of severe and fatal toxicity during treatment with fluorouracil. All patients should be tested for DPD deficiency before initiation (cycle 1) to minimise the risk of these reactions

Dose Modifications

The dose modifications listed are for haematological, liver and renal function 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.

Please discuss all dose reductions / delays with the relevant consultant before prescribing, if appropriate. The approach may be different depending on the clinical circumstances. The following is a general guide only.

Haematological

Prior to prescribing the following criteria must be met;

Criteria	Eligible Level
Neutrophils	Equal to or more than $1.5x10^9$/L
Platelets	Equal to or more than $75x10^9$/L

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. Dose limiting toxicities include diarrhoea, abdominal pain, emesis, stomatitis and palmar-plantar erythrodysesthesia among others.

Kidney / Liver Impairment

Drug	Hepatic	Renal
Fluorouracil	If the bilirubin is more than 85umol/L and / or the AST more than 180 fluorouracil is contra-indicated. In moderate hepatic impairment consider reducing the dose by 30% and for severe impairment by 50%	A dose adjustment is only required in severe renal impairment.

Regimen

35 day cycle for 1 cycle

Drug	Dose	Days	Route
Fluorouracil	225mg/m^2/day (1575mg/m^2/7 days)	1, 8, 15, 22, 29	Intravenous infusion over 7 days.

If this product is being made in an unlicensed unit the patient will need to be scheduled in the afternoon. The pump is a 7 day treatment and the expiry from an unlicensed unit is 7 days. It cannot be made in advance.

Dose Information

- Fluorouracil will be dose banded in accordance with the national dose bands (50mg/ml infusion)

Administration Information

Extravasation

- Fluorouracil – inflammitant

Other

- Central venous access and use of an ambulatory infusion pump is required.

Additional Therapy

- Antiemetics

  As take home medication;

  - metoclopramide 10mg three times a day when required oral

- Oral loperamide 4mg after the first loose stool then 2-4mg four times a day when required for the relief of diarrhoea (maximum 16mg/24 hours).

- Gastric protection with a proton pump inhibitor or a H_2 antagonist may be considered in patients considered at high risk of GI ulceration or bleed

References

1. Allegra C et al. Neoadjuvant 5-fu or capecitabine plus radiation with or without oxaliplatin in rectal cancer patients: A phase III randomised clinical trial. J NCI Natl Cancer Institute (2015): 107 (11).
2. Hospira UK Ltd (2020). Fluorouracil 50mg/ml injection summary for product characteristics. Available from: www.medicines.org.uk (accessed 05/08/2022).

REGIMEN SUMMARY

Day 1

1. Fluorouracil 1575mg/m^2 intravenous infusion over 7 days

Take Home Medicines (day 1 only)

2. Metoclopramide 10mg three times a day when required oral
   Administration instructions:
   Please supply 28 tablets or nearest equivalent original pack size.

3. Loperamide 4mg after the first loose stool and 2mg after each subsequent loose stool to a maximum of 16mg in 24 hours
   Administration Instructions
   Take 4mg after the first loose stool and then 2mg after each subsequent loose stool to a maximum of 16mg in 24 hours. Please supply one original pack size

Day 8, 15, 22, 29

1. Fluorouracil 1575mg/m^2 intravenous infusion over 7 days

DOCUMENT CONTROL

Version	Date	Amendment	Written By	Approved By
1	Aug 2022	None	Alexandra Pritchard Pharmacist	Dr Sathish Harinarayanan (consultant oncologist)

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 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 which occur as a result of following these guidelines.