

Chemotherapy Protocol
LUNG CANCER – SMALL CELL (SCLC)
TOPOTECAN
(Oral)

Regimen

- SCLC – Topotecan PO

Indication

- Treatment of relapsed SCLC when re-treatment with the first line therapy is not considered appropriate and the combination of cyclophosphamide, doxorubicin and vincristine (CAV) is contra-indicated.
- WHO performance status 0, 1, 2
- Palliative intent

Toxicity

Drug	Adverse Effect
Topotecan (oral)	Diarrhoea, anorexia, abdominal pain, pruritis

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

Monitoring

Disease

- A baseline chest x-ray should be performed before starting treatment and up to date (ideally within 1 month) cross section imaging should also be performed

Regimen

- FBC, LFTs and U&Es prior to each cycle
- A chest x-ray should be performed before each cycle

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.

Haematology

Prior to prescribing on day one of cycle one the following criteria must be met;

Criteria	Eligible Level
Neutrophil	equal to or more than $1.5 \times 10^9/L$
Platelets	equal to or more than $100 \times 10^9/L$

Consider blood transfusion if patient symptomatic of anaemia or haemoglobin less than 8g/dL

Subsequently if the neutrophils are less than $1 \times 10^9/L$ then in the first instance delay treatment for 7 days. If counts recover at this point continue at the initial dose. If counts remain low or there has been an episode of grade 3 or above neutropenia continue with treatment using a dose of $1.9 \text{mg}/\text{m}^2/\text{day}$. If the myelosuppression recurs despite this dose reduction consider either stopping treatment or reducing the dose to $1.5 \text{mg}/\text{m}^2/\text{day}$.

If the platelets are less than $100 \times 10^9/L$ then in the first instance delay treatment for 7 days. If the counts recover at this point continue at the initial dose. If the counts still fall within this range or dropped below $25 \times 10^9/L$ continue using a dose of $1.9 \text{mg}/\text{m}^2/\text{day}$. If the myelosuppression recurs despite this dose reduction consider either stopping treatment or reducing the dose to $1.5 \text{mg}/\text{m}^2/\text{day}$.

In clinical trials, topotecan was discontinued if the dose needed to be reduced below $1.5 \text{mg}/\text{m}^2/\text{day}$.

Other

For patients who experience a grade 3 or 4 diarrhoea, the dose should be reduced to $1.9 \text{mg}/\text{m}^2/\text{day}$ for subsequent courses. Patients with Grade 2 diarrhoea may need to follow the same dose modification guidelines.

Hepatic Impairment

Drug	Bilirubin $\mu\text{mol}/L$		AST/ALT units	Dose (%of original dose)
Topotecan	Limited information available			

Renal Impairment

Drug	Creatinine Clearance (ml/min)	Dose (% of original dose)
Topotecan	The recommended monotherapy dose of oral topotecan in patients with small cell lung carcinoma with a creatinine clearance between 30 and 49 ml/min is 1.9 mg/m ² /day for five consecutive days. If well tolerated, the dose may be increased to 2.3 mg/m ² /day in subsequent cycles	

Regimen

Topotecan is available as 0.25mg and 1mg capsules. Hence, doses must be rounded to the nearest 0.25mg or an alternate day dosing schedule used to facilitate the administration of the correct dose. It must be made clear to all staff, including those in the community, that this is a short course of therapy that must not be continued. It should be prescribed from secondary care only.

21 day cycle until disease progression or intolerance (set 4 cycles in Aria)

Drug	Dose	Days	Administration
Topotecan	2.3mg/m ² /day	1-5 incl	Oral

Dose Information

- Doses will be rounded to the nearest 0.25mg capsule

Administration Information

- Topotecal (oral) should be swallowed whole, not chewed, with plenty of water

Additional Therapy

- Antiemetics (moderate)
 - metoclopramide 10mg three times a day oral for 5 days
- 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).
- Growth factors may be considered according to local policy.
- Gastric protection with a proton pump inhibitor or a H₂ antagonist may be considered in patients considered at high risk of GI ulceration or bleed
- SCLC can be very sensitive to chemotherapy. This may lead to the development of tumour lysis syndrome at the start of therapy. For those at risk individuals' allopurinol should be prescribed. This should begin the day before chemotherapy treatment and continue for as long as a significant chemosensitive tumour bulk remains. Normally one cycle suffices.

Additional Information

- The National Patient Safety Agency Alert NPSA/2008/RRR001 must be adhered to in relation to oral chemotherapy.

Coding (OPCS 4.5 version 2)

- Procurement – X70.4
- Delivery – X73.1

References

1. National Institute for Health and Clinical Excellence (2009). Technology Appraisal 184. Topotecan for the Treatment of Relapsed Small Cell Lung Cancer. DOH: London

REGIMEN SUMMARY

Topotecan PO

Day One

1. Topotecan 2.3mg/m²/day once daily for 5 days oral
2. Metoclopramide 10mg three times a day for 5 days oral

DOCUMENT CONTROL

Version	Date	Amendment	Written By	Approved By
1.2	December 2013	CSCCN removed from header Toxicities removed Tables used throughout Renal and hepatic function updated Metoclopramide dose changed to 10mg TDS OPCS updated Name added to top of summary page Stat removed from loperamide Hospitals and disclaimer added	Dr Deborah Wright Pharmacist	Donna Kimber Pharmacy Technician
1.1	January 2011	Coding added	Dr Deborah Wright Pharmacist	Donna Kimber Pharmacy Technician

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 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.