NHS
North West Coast
Strategic Clinical Networks

Chemotherapy Protocol

DRUG REGIMEN
Niraparib

Indication for use
Recurrent platinum-sensitive epithelial ovarian, fallopian tube, or primary peritoneal cancer following a complete or partial response to platinum-based chemotherapy

Regimen
Niraparib 300mg orally daily

(A starting dose of 200 mg for patients weighing less than 58 kg may be considered)

Treatment is given continuously; dispensed monthly

Investigation prior to initiating treatment

1. **Obtain a complete blood count (CBC)**
   - Prior to the initial dose of niraparib, a CBC should be obtained for baseline assessment and for eligibility
   - A CBC should be performed ***weekly*** for the ***first month***
   - Continue ***monthly*** thereafter for the ***next 11 months***
   - Periodically monitored thereafter for clinically significant changes
2. **Monitor blood pressure**
   - Prior to the initial dose of niraparib, blood pressure shall be measured for baseline monitoring
   - Continue to measure ***monthly*** for the ***first year*** and periodically thereafter, as deemed appropriate
   - Hypertension can be medically managed with antihypertensive medications or adjustment of niraparib dose
3. **Perform pregnancy test**
   - Niraparib should not be given to any woman who is pregnant or anticipates becoming pregnant
   - A pregnancy test must be performed on all women of ***childbearing potential*** prior to the initial dose of niraparib
   - If the urine test is positive or borderline (unable to confirm a negative), a blood test will be required
   - Any patient who becomes pregnant during the course of the treatment must immediately be discontinued from niraparib treatment

Cautions
There are no data in patients with severe renal impairment or end stage renal disease undergoing haemodialysis; niraparib should be used with caution in these patients. No dosage adjustment is needed with mild to moderate hepatic impairment. There are no data in patients with severe hepatic impairment, use with caution in these patients

Investigations and consultations prior to each cycle
Repeat investigations prior to initiating treatment

Acceptable levels for treatment to proceed (if outside these levels defer one week or contact consultant)
Adequate organ function and haematology parameters; ANC 1,500/µL; Platelets 100,000/µL; Hemoglobin 9g/dL

Side Effects
Most common adverse reactions (incidence ≥10%) are thrombocytopenia, anaemia, neutropenia, leukopenia, palpitations, nausea, constipation, vomiting, abdominal pain/distention, mucositis/stomatitis, diarrhoea, dyspepsia, dry mouth, fatigue/asthenia, decreased appetite, urinary tract infection, AST/ALT elevation, myalgia, back pain, arthralgia, headache, dizziness, dysgeusia, insomnia, anxiety, nasopharyngitis, dyspnea, cough, rash, and hypertension

Dose Modification Criteria

May be implemented at any time for any grade of adverse events, when deemed in the best interest of the patient. Not all AEs require dose modification. Use best clinical judgment for AE management. No more than 2 dose reductions will be allowed based on treatment side effects. If further dose reduction below 100mg/day is required, niraparib treatment needs to be discontinued

Dose Modification Guidelines for Haematological Adverse Events

Platelet count <100,000/µL	First occurrence: • Withhold niraparib for a maximum of 28 days and monitor blood counts weekly until platelet counts return to ≥100,000/µL • **Resume niraparib at same or reduced dose.** • **If platelet count reduced below <75,000/µL, resume at a reduced dose**
	Second occurrence: • Withhold niraparib for a maximum of 28 days and monitor blood counts weekly until platelet counts return to ≥100,000/µL • Resume niraparib at a reduced dose • Discontinue niraparib if the platelet count has not returned to acceptable levels within 28 days of the dose interruption period, or if the patient has already undergone dose reduction to 100 mg once daily*
Neutrophil <1,000/µL or Haemoglobin <8 g/dL	• Withhold niraparib for a maximum of 28 days and monitor blood counts weekly until neutrophil counts return to ≥1,500/µL or haemoglobin returns to ≥9 g/dL • Resume niraparib at a reduced dose • Discontinue niraparib if neutrophils and/or haemoglobin have not returned to acceptable levels within 28 days of the start of the dose interruption period, or if the patient has already been dose reduced to 100mg*

*If myelodysplastic syndrome or acute myeloid leukemia (MDS/AML) is confirmed, discontinue niraparib

Specific Information on Administration

Food does not significantly affect the absorption of niraparib, therefore niraparib may be taken without regards to meals. Patients should be encouraged to take their dose of niraparib at approximately the same time each day. Bedtime administration may be a potential method for managing nausea

If a patient vomits or misses a dose of niraparib, an additional dose should not be taken and the next dose should be taken at the regularly scheduled time.

THIS PROTOCOL HAS BEEN DIRECTED BY DR YIANNAKIS, DESIGNATED LEAD CLINICIAN FOR GYNAECOLOGICAL CANCERS

RESPONSIBILITY FOR THIS PROTOCOL LIES WITH THE HEAD OF SERVICE

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