DRUG REGIMEN
Gemcitabine- single agent (ovarian/fallopian/primary peritoneal cancer)

Indication for use
Platinum resistant disease (progression within 6 months of completing a platinum-containing chemotherapy protocol) or platinum refractory disease (progression while being treated with platinum), after paclitaxel (taxane-resistant)
PS ECOG 3 or better

Regimen

Day 1	Gemcitabine	1000mg/m^2	IV	in 250ml N saline over 30mins
Day 8	Gemcitabine	1000mg/m^2	IV	in 250ml N saline over 30mins

Repeat cycle every 21 days for 6-8 cycles, interval assessment after 3 cycles.

Investigation prior to initiating treatment
FBC, U&Es, Calculated creatinine clearance, LFTs, CA125

CT staging Chest, Abdomen and Pelvis for comparison

Cautions
History of thrombocytopenia
Liver impairment

Investigations and consultations prior to each cycle
Day1: FBC, U&Es, LFTs
Day 8: FBC. If need follow-up abnormal levels for U&Es, LFTs.
CA125 : monthly or can be retrospectively looked at

Consultation prior to each cycle

Acceptable levels for treatment to proceed (if outside these levels defer one week or contact consultant)

Haematological Toxicity:
Proceed on day 1 if platelets ≥ 100, neuts ≥ 1. Delay 1 week on day 1 if platelets ≤ 99, neuts ≤0.9
Proceed on Day 8 if platelets ≥ 75, neuts ≥ 1
Omit Day 8 if platelets < 75 or neuts < 1.0 and proceed to the next cycle with dose reduced 20%

Dose Modification Criteria
20% dose reduction if there is a delay >1 week, if there has been a previous delay of more than 2 cycles or if the patient experiences neutropenic sepsis
Hepatic impairment: If bilirubin > 27µmol/L, consider reducing dose to 800mg/m^2
Renal impairment: No safety data in patients with CrCl < 30mL/min. Consider dose reduction (clinical decision)

Side Effects
Gastrointestinal: nausea, vomiting ,diarrhoea, constipation, mucositis
General disorders Malaise, fever, chills, urticaria, flu-like syndrome, dizziness during infusion
Oedema/peripheral oedema - including facial oedema
Haematological: neutropenia, anaemia, thrombocytopenia
Hepatobiliary: elevation of liver transaminases (AST and ALT), alkaline phosphatase and bilirubin.
Hypersensitivity reactions: Skin rash, urticaria, erythematous rash, and fever with no apparent cause or pruritus.
Musculoskeletal: backpain, myalgia

Pulmonary Toxicity: acute shortness of breath may occur. Discontinue treatment if drug-induced pneumonitis is suspected.

For Grade 3 toxicity: delay treatment until resolution of symptoms, then resume at 700-800 mg/m^2
If Grade 3 toxicity persists, discontinue gemcitabine
For Grade 4 toxicity, discontinue treatment
Doses reduced for toxicity should not be re-escalated

Specific Information on Administration

Drug Interactions Warfarin/coumarin anti-coagulants – can increase anticoagulant effect or cause fluctuations. Avoid if possible or consider switching patient to a LMWH during treatment. If patient continues to take an oral anticoagulant, INR must be checked at least once a week and dose adjusted accordingly.

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THIS PROTOCOL HAS BEEN DIRECTED BY DR BADEA
DESIGNATED LEAD CLINICIAN FOR RESPONSIBILITY FOR THIS PROTOCOL LIES WITH THE HEAD OF SERVICE

DATE: **November 2018**
REVIEW: **November 2020**
VERSION: **1**