Gemcitabine

Indication

Adjuvant treatment of resected carcinoma of the pancreas
Locally advanced or metastatic carcinoma of the pancreas
Platinum resistant ovarian/fallopian/primary peritoneal cancer
Advanced non-small cell lung cancer

Regimen details

Day	DRUG	FLUID	TIME
1,8 & 15	Gemcitabine 1000mg/m²	250mls 0.9% sodium chloride	30 Mins

(Also give on day 22 of cycle 1 in metastatic pancreatic cancer only)

Cycle frequency

Every 28 days

Number of cycles

6 cycles for adjuvant treatment
Until disease progression for metastatic disease

Administration

30-minute infusion in 0.9% Sodium Chloride 250mls (longer infusion times lead to increased toxicity).
Use licensed manufactured bags where available.

Pre-medication

None specific

Emetogenicity

Low

Additional supportive medication

None

Extravasation

Neutral

Investigations – pre first cycle

Investigation	Validity period
FBC	14 days
U+E (including creatinine)	14 days
LFT (including AST)	14 days

Investigations –pre subsequent cycles

FBC, U+E (including creatinine), LFT (including AST)

Standard limits for administration to go ahead

If blood results not within range, authorisation to administer **must** be given by prescriber/ consultant.

Investigation	Limit
Neutrophil count	≥ 1.5 (on day 1), 1.0 (on day 8 & 15) x 10^9/L
Platelet count	≥ 100 x 10^9/L
Creatinine clearance	≥ 30 mL/min
Bilirubin	≤ 1.5 x ULN

Dose modifications

Day 1
• If neutrophils between 1.0-1.5 or platelets <100 delay treatment by one week.

• If there is recovery after one week then continue at 100% dose.

• If no recovery after 2 weeks or if neutrophils on day 1 <1.0 then delay by one week and reduce dose to 75%

Days 8 or 15
If neutrophils <1 or platelets <100; omit the dose and give future doses at 75%

Neutropenic Sepsis:
Following an episode of neutropenic sepsis subsequent courses should be given at 75% dose.

Non-haematological Toxicity
Modifications are not required normally. In exceptional cases treatment delay may be necessary until the toxicity has resolved. If this happens then a 25% reduction should be made for subsequent courses
The maximum allowable treatment delay is 3 weeks. Any patient whose treatment is delayed for longer than three weeks should discontinue therapy

Liver transaminases: Abnormalities of liver transaminases occur in up to two-thirds of patients but changes are not progressive and rarely cause problems

Nausea and Vomiting: This occurs in about 30% of patients and responds to standard anti-emetics

Skin rash: This is seen in about 25% of patients, mild, and responds to topical preparations

Flu-like illness: This occurs in about 20% of patients and is normally mild

Oedema: Peripheral oedema has been seen in up to 30% of patients and normally responds to stopping treatment. Pulmonary oedema has been reported rarely

Severe dyspnoea, ARDS, haemolytic ureaemic syndrome: discontinue treatment

Adverse effects - for full details consult product literature/ reference texts

Myelosuppression – all cell lines
Occasionally: rash and mild SOB, 'flu like' symptoms
Rarely: severe dyspnoea, ARDS, haemolytic ureaemic syndrome - discontinue treatment if these occur

Significant drug interactions – for full details consult product literature/ reference texts

Warfarin/coumarin anticoagulants: increased or fluctuating anticoagulant effects. Avoid if possible, consider switching patient to a low molecular weight heparin during treatment or if the patient continues taking an oral anticoagulant monitor the INR at least once a week and adjust dose accordingly.

Gemcitabine is a radiosensitiser.

Additional comments

References

Burris et al. Improvements in Survival and Clinical Benefit With Gemcitabine as First-Line Therapy for Patients With Advanced Pancreas Cancer: A Randomized Trial. J Clin Oncol. 1997 Jun;15(6):2403-13

Guidance on the use of gemcitabine for the treatment of pancreatic cancer Technology appraisal guidance Reference number:TA25 Published: 08 May 2001

THIS PROTOCOL HAS BEEN DIRECTED BY DR MITCHELL, DESIGNATED LEAD CLINICIAN FOR UPPER GI CANCER

RESPONSIBILITY FOR THIS PROTOCOL LIES WITH THE HEAD OF SERVICE

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