Secondary Endpoint: Pharmacokinetic Profile

End point type	Secondary
End point title	Pharmacokinetic profile of Amphinex (fimaporfin) and gemcitabine in plasma
End point description: The following pharmacokinetic parameters were used to determine the PK profile of fimaporfin and gemcitabine: elimination half-life, total clearance, volume of distribution, maximum plasma concentration, area under the plasma concentration versus time curve.	
Endpoint timeframe: Amphinex (fimaporfin) PK samples collected at the following timepoints: ≤24 hrs before Amphinex administration, and at 2–3 min, 30 min±5 min, 4 hrs±30 min, 24 hrs±2 hrs (day 1), Day 6±1 day, Week 6±2 weeks and 3 months±2 weeks post Amphinex administration. Gemcitabine PK samples collected at the following timepoints: ≤24 hrs before gemcitabine infusion, directly after stopping infusion, and at 15 min±2 min, 30 min±5 min, 60 min±5 min, 90 min±5 min, 2 hrs±10 min, 5 hrs±1 hr and 24 hrs±2 hrs post-gemcitabine infusion.	

Endpoint Values	Total
Elimination half-life (fimaporfin) Units: days	
Range	18 to 107
Total clearance (fimaporfin) Units: ml/(hrs*kg)	
Range	0.058 to 0.359
Volume of distribution, elimination phase (fimaporfin) Units: ml/kg	
Range	112 to 294
Elimination half-life (gemcitabine) Units: minutes	
Mean	31
Total clearance (gemcitabine) Units: $l/(min*m^2)$	
Mean	2
Volume of distribution, elimination phase (gemcitabine) Units: l/m^2	
Mean	117
Fimaporfin: The increase in maximum plasma concentration (C_{max}) was proportional to the increase in dose while the increase in area under the plasma concentration versus time curve from time 0 to infinity (AUC_{0-inf}) was higher than the increase in dose.	

Gemcitabine: There was a large variability in the estimated exposure to gemcitabine across the patient group. Both C_{max} and $AUC_{0\text{-}inf}$ varied by a factor of almost 30 between the lowest and highest values

Statistical Analysis of Endpoint

No statistical analyses for this endpoint.