PHOTOSTENT-02

Porfimer sodium photodynamic therapy plus stenting versus stenting alone in patients with advanced or metastatic cholangiocarcinomas and other biliary tract tumours: a multi-centre, randomised, phase III study

Clinical Study Report

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EudraCT Number	2005-001173-96
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Sponsorship Number	UCL/05/003
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IMPs/treatment:	Porfimer Sodium photodynamic therapy
Indication:	Patients with advanced or metastatic cholangiocarcinomas and other biliary tract tumours
Treatment:	Eligible patients were randomised to receive either biliary stenting alone (Arm A) or photodynamic therapy (PDT) plus biliary stenting (Arm B). **Arm A** Stenting alone **Arm B** Photodynamic therapy plus stenting
Start date:	19/07/2007 (first site open)
End date:	18/12/2009 (trial closed to recruitment due to urgent safety measure). End of trial submitted 26/07/2011.
Aim:	To determine whether porfimer sodium photodynamic therapy in addition to standard treatment confers an overall survival benefit in patients with locally advanced non-resectable biliary tract carcinoma.
Endpoints:	• Primary: o Overall survival • Secondary: o Progression free survival o Toxicity o Quality of life
Target sample size	240 patients
Justification of premature ending of trial:	Interim Independent Data Monitoring Committee (IDMC) review on 92 patients recruited from July 2007 and November 2009 (46 patients in each group) revealed that the group of patients who received PDT + stenting had a significantly shorter overall survival than those who had stenting alone. The IDMC therefore recommended stopping recruitment. Follow up continued on patients who had already been recruited.
Number of patients still receiving treatment at termination:	0
Proposed management of patients receiving treatment at time of termination:	N/A
Study achieved its objective?	The primary objective was to determine the value of PDT in addition to stenting, on the overall survival of BTC patients. Interim analysis indicated that PDT in addition to stenting had a detrimental effect on overall survival.
Main findings:	In total 92 patients were recruited into the Photostent0-02 trial. Patients were well balanced for prognostic factors and prior therapy. After a median follow-up of 5.0 months, overall survival was 5.6 months for Arm B versus 8.5 months for Arm A. The treatment effect was similar in patients with locally advanced and metastatic disease and between randomising centres. Median progression free survival was 3.6 and 4.1 months in Arms B and A. Although overall survival was significantly improved among those who had subsequent chemotherapy vs. those who did not (11.1 vs. 4.8 months, p=0.001), adjusting for this only reduced the PDT + stenting hazard ratio from 1.82 to 1.61 suggesting other factors contributed to the excess risk in the PDT arm. There were no significant differences in grade 3+ toxicities between the two arms, and there were no grade 3+ side effects associated with the PDT treatment.
Arrangement for publications:	Ann Oncol (2010) 21 (suppl 8): viii250-viii263; Abstr 8020 . Manuscript is in preparation for submission to peer reviewed journal.
Arrangements for dissemination of the research, including any feedback to participants:	N/A