Photodynamic laser therapy using Foscan for non-curatively-resectable bile duct carcinoma

Published: 22-06-2010
Last updated: 02-05-2024

To assess efficacy and safety of temoporfin (Foscan*) photodynamic therapy in the treatment of locally advanced perihilar bile duct carcinoma without distant metastases.

Ethical review	Approved WMO
Status	Pending
Health condition type	Hepatobiliary neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON35016

Source
ToetsingOnline

Brief title
Foscan-PDT for CCA

Condition

- Hepatobiliary neoplasms malignant and unspecified

Synonym
cancer of the biliary tract, cholangiocarcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Biolitec Inc.;Dublin;Ireland ,Select

Intervention

Keyword: cholangiocarcinoma, Foscan, PDT

Outcome measures

Primary outcome

Rate of local response and depth of tumoricidal tissue penetration of Foscan*-PDT.

Secondary outcome

(i) Progression-free survival time, overall survival time; (ii) rate of systemic response; (iii) Toxicity using WHO criteria and criteria for local toxicity in the biliary system.

Study description

Background summary

Photodynamic therapy (PDT) can be defined as photochemotherapy. A photosensitizing drug known to accumulate in tumor tissue is administered. Subsequently, the tumor tissue is exposed to laser light of appropriate wave length suitable to activate the photosensitizing drug. In presence of oxygen the activated photosensitizer leads to phototoxic reactions in the tumor tissue. Two prospective, single-arm, open phase II trials on 9 and 23 patients, respectively, with non-resectable proximal bile duct cancer (29 Bismuth type IV, 3 type III) showed significantly improved palliation (cholestasis, performance status, quality of life indices) and a clear trend for prolonged survival (median 12 - 14 months, respectively) with PDT using the hematoporphyrin derivative, sodium porfimer (Photofrin*). Prolonged survival time with PDT using Photofrin* as compared with biliary drainage only was confirmed in a randomized trial. Tumoricidal tissue penetration is limited to 4-5 mm with Photofrin*. PDT using temoporfin (Foscan*, Biolitec Pharma, Edinburgh, UK) shows deeper tumoricidal tissue penetration of > 8mm and high tumor selectivity and has been validated for PDT of oropharyngeal cancers and been licensed for that indication in the EU.

Study objective

To assess efficacy and safety of temoporfin (Foscan*) photodynamic therapy in the treatment of locally advanced perihilar bile duct carcinoma without distant metastases.

Study design

Open-label Phase-II trial of Foscan* (temoporfin) photodynamic therapy in patients with non-resectable perihilar bile duct carcinoma in clinical stage M0 (without liver or peritoneal metastases according to clinical or surgical staging)

Intervention

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Study burden and risks

The burden associated with participation in this study is expected to be confined to the few more days of hospitalisation after the endoscopic procedure during which PDT is performed, and the potential pain caused by the PDT. This extra burden is contrasted with the potentially improved palliation and prolonged survival, which was shown in earlier studies. For patients without the possibility of a curative surgical resection, a group which is characterized by a very poor prognosis, more evidence for the efficacy and safety of Foscan-PDT would provide the rationale and possiblity to offer these patients a new therapeutic modality to alleviate their suffering.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* bile duct carcinoma proven by histology in advanced or non-operable stage or tumor extension:
a) Bismuth type III or IV (not resectable with R0-margins)
b) Bismuth type I or II, if resective surgery is contraindicated for old age
or poor surgical risk of patient
* sufficient general condition to undergo PDT (Karnofsky status > 30%)
* age > 19 years
* access to common bile duct (either via endoscopy after sphincterotomy or percutaneously after transhepatic drainage),
* informed written consent for PDT (Appendix 3)

Exclusion criteria

* porphyria or other diseases exacerbated by light
* known intolerance or allergies to porphyrin derivatives
* a planned surgical procedure within the next 30 days
* coexisting ophthalmic disease likely to require slit lamp examination within the next 30 days
* impaired kidney or liver function (creatinine > 2.5x elevated, INR > 2.2 on vitamin K),
* leukopenia (WBC < 2000/cmm) or thrombopenia (< 50000/cmm),
* cytotoxic chemotherapy within the past 4 weeks.
* pregnancy (or unsafe contraception for 6 months after PDT)
* accompanying/complicating disease with very poor prognosis (expected survival < 6 weeks),

* proven advanced peritoneal carcinomatosis (PET scan imaging, ascites positive for tumor cells)
* acute destructive bacterial cholangitis (empyema, abscess, cholangitis with confluent liver necrosis)

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2010
Enrollment:	8
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Foscan
Generic name:	temoporfin
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Application type:	First submission

Review commission: METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2005-004866-17-NL
CCMO	NL31169.018.10