A pilot study to determine the feasibility of Stereotactic Body Radiation Therapy following Chemotherapy for Unresectable perihilar CholangioCarcinoma

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To assess feasibility of SBRT as add on treatment after standard chemotherapy.

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

Summary

ID

NL-OMON45647

Source
ToetsingOnline

Brief title
the STRONG trial

Condition

- Hepatobiliary neoplasms malignant and unspecified
- Hepatobiliary neoplasms malignant and unspecified

Synonym
cholangiocarcinoma, perihilar

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cholangiocarcinoma, feasibility, quality of life, stereotactic body radiation

Outcome measures

Primary outcome

The primary endpoint of this study is feasibility measured by radiotherapy

induced toxicity according to CTC v4.0.3.

Secondary outcome

-Quality of life

-Local progression

-Progression free survival

-Overall survival

-Cellular radiosensitivity.

Study description

Background summary

For patients with perihilar cholangiocarcinoma, surgery is the only treatment modality that can result in cure. Unfortunately, in the majority of these patients the tumors are found to be unresectable at presentation due to local invasive tumor growth or the presence of distal metastases. For patients with unresectable cholangiocarcinoma palliative chemotherapy is the standard treatment yielding an estimated median overall survival of 12-15.2 months. There is no evidence from randomized trials that support the routine use of stereotactic body radiation therapy (SBRT) for cholangiocarcinoma. However, small and most often retrospective studies combining chemotherapy with SBRT showed promising results with overall survival reaching up to 33-35 months.

Based upon these observations, we designed a local feasibility trial with SBRT after chemotherapy in patients with unresectable perihilar cholangiocarcinoma in order to try to confirm the observed tolerability of adding SBRT to standard chemotherapy. The expected time to include the required patients for this pilot

study will be one year.

Study objective

To assess feasibility of SBRT as add on treatment after standard chemotherapy.

Study design

Local feasibility trial.

Intervention

SBRT will be delivered in 15 fractions of 3 to 4.5Gy after 8 cycles of chemotherapy. In case of toxicity causing premature termination of systemic treatment, the patient can still proceed to SBRT.

Study burden and risks

Studies evaluating toxicity of SBRT delivered in 15 fractions for intrahepatic cholangiocarcinoma provide evidence that SBRT is a relatively safe treatment with acceptable complication risks.

The risk of biliary toxicity with the SBRT protocol used in this trial is expected to be <10%. Dose limitations for the surrounding organs comply with internationally accepted recommendations such as the Quantitative Analyses of Normal Tissue Effects in the Clinic (QUANTEC). Expected associated toxicity such as stomach or bowel perforation, is expected to be low (<5%). The main risk associated with fiducial marker implantation is intrahepatic bleeding, which is expected to be rare. In order to minimize this risk of complications, the implantation will be carried out by a well-trained interventional radiologist. Patient will remain hospitalized during at least 2-3 hours after the implantation to assess for any procedural complications.

A DSMB will be installed if the Ethical Committee estimates that this is needed due to the fact that this is a feasibility study. However, the expected risk associated with the participation in this trial is low. No interim analysis is planned for this study.

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

- Patients diagnosed with perihilar cholangiocarcinoma according to the criteria of the Mayo Clinic:
-Positive or strongly suspicious intraluminal brush or biopsy or,
-A radiographic malignant appearing stricture plus either:
-CA 19-9>100 U/ml in the absence of acute bacterial cholangitis, or
-polysomy on FISH, or
-a well-defined mass on cross sectional imaging
-One tumor mass ;
-Unresectable tumor;
-Finished chemotherapy treatment with Gemcitabine and Cisplatin, preferably 8 cycles; If less cycles are given, patients are still eligible for this study.
-T1-T4 (AJCC staging 7th edition), before chemotherapy;
-N0-N1 (AJCC staging 7th edition), radiologically or pathologically suspect, before chemotherapy;
-Measurable disease to be selected as a target on CT/MRI-scan, according to RECIST criteria, after chemotherapy within 6 weeks prior to inclusion
-Tumor visibility on CT;
-If liver cirrhosis is present, it should be well compensated, with Child-Pugh grade A;
-Age * 18 years;

-ECOG performance status 0-1;
-Bilirubin *1.5 times normal value, AST/ALT *5 times ULN, within 6 weeks prior to inclusion;
-Platelets * 50x10E9/ l, Leukocytes > 1.5x10E9/l, Hb > 6 mmol/l, within 6 weeks prior to inclusion;
-Written informed consent, after chemotherapy;
-Willing and able to comply to the follow-up schedule;
-Able to start SBRT within 12 weeks after completion of chemotherapy.

Exclusion criteria

-Eligibility for resection;
-Prior surgery or transplantation;
-Multifocal tumor;
-Tumor extension in stomach, colon, duodenum, pancreas or abdominal wall;
-N2, (AJCC staging 7th edition), radiologically or pathologically suspect, before chemotherapy;
-Distant metastases;
-Progression (local or distant) during or after chemotherapy
-Ascites;
-Previous radiotherapy to the liver;
-Current pregnancy

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-11-2017
Enrollment:	0
Type:	Actual

Ethics review

Approved WMO Date:	31-08-2017
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL60588.078.17