

# Photodynamic therapy for the palliation of non-resectable proximal cholangiocarcinoma.

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON20863

### Source

NTR

### Brief title

PDT

### Health condition

non-resectable bile duct tumor

## Sponsors and support

**Primary sponsor:** no sponsor

**Source(s) of monetary or material Support:** no funds

## Intervention

## Outcome measures

### Primary outcome

Survival.

### Secondary outcome

1. Number of repeat invasive procedures;
2. Length hospitalization;
3. Level of cholestasis;
4. Rates of cholangiographic tumor response;
5. Karnofsky performance;
6. Quality of life;
7. Adverse events.

## Study description

### Background summary

N/A

### Study objective

Due to tumoricidal effect of PDT , it is expected that the central bile ducts remain free from tumor and so better and prolonged drainage can be achieved leading to better QoL and survival.

### Intervention

Endoscopic treatment with plastic endoprotheses (=current standard).

Versus

Endoscopic treatment with plastic endoprotheses with, during this procedure, internal illumination of the tumor with light of a specific wavelength after infusion of a photosensitizer.

## Contacts

### Public

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## Eligibility criteria

### Inclusion criteria

1. Proven irresectable bile duct tumor;
2. Adequate drainage bile ducts with plastic endoprothese(s);
3. Karnofsky index > 30%;
4. Age > 18 year.

### Exclusion criteria

1. Porfyrria;
2. Previous chemo-/or radiotherapy;
3. Presence of metallic endoprothese(s);
4. Active cholangitis;
5. Primary sclerosing cholangitis;
6. Karnofsky index < 30%.

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Active

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-01-2005
Enrollment:	75
Type:	Anticipated

## Ethics review

Positive opinion	
Date:	30-08-2005
Application type:	First submission

## 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

NTR-new

NTR-old

Other

ISRCTN

### ID

NL128

NTR162

: 04/161

ISRCTN43588830

## Study results

### Summary results

N/A