

Photodynamic therapy for the palliation of non-resectable proximal cholangiocarcinoma

Submission date 20/12/2005	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 20/12/2005	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 18/11/2008	Condition category Cancer	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
04/161; NTR162

Study information

Scientific Title

Acronym

PDT

Study objectives

Due to tumouricidal effect of photodynamic therapy (PDT), it is expected that the central bile ducts remain free from tumour and so better and prolonged drainage can be achieved leading to better quality of life (QoL) and survival.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from the local medical ethics committee

Primary study design

Interventional

Study design

Randomised, active controlled, parallel group trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Bile duct tumour, cholangiocarcinoma

Interventions

Endoscopic treatment with plastic endoprotheses (= current standard) versus endoscopic treatment with plastic endoprotheses with, during this procedure, internal illumination of the tumour with light of a specific wavelength after infusion of a photosensitiser.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Survival

Key secondary outcome(s)

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

Completion date

01/01/2008

Eligibility

Key inclusion criteria

1. Proven irresectable bile duct tumour
2. Adequate drainage bile ducts with - plastic endoprothese(s)
3. Karnofsky index greater than 30%
4. Aged greater than 18 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

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

Date of first enrolment

01/01/2005

Date of final enrolment

01/01/2008

Locations

Countries of recruitment

Netherlands

Study participating centre

Academic Medical Centre

Amsterdam

Netherlands

1105 AZ

Sponsor information

Organisation

Academic Medical Centre (AMC) (Netherlands)

ROR

<https://ror.org/03t4gr691>

Funder(s)

Funder type

Not defined

Funder Name

Not provided at time of registration

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration