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Photodynamic therapy for the palliation of non-resectable proximal cholangiocarcinoma

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised, active controlled, parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
Survival

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

Overall study start date
01/01/2005

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
75

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)

Sponsor details
Meibergdreef 9
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1105 AZ

Sponsor type
University/education

Website
http://www.amc.uva.nl/

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Not defined

Funder Name

Not provided at time of registration

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration