# Palliative Chemotherapy (2nd line) with Imatinib (Glivec™) in Patients with Bile Duct Cancer

<b>Submission date</b> 02/02/2006	<b>Recruitment status</b> Stopped	[X] Prospectively registered [ ] Protocol
Registration date	Overall study status	Statistical analysis plan
27/02/2006	Stopped	Results
Last Edited	Condition category	Individual participant data
01/09/2009	Cancer	Record updated in last year

# Plain English summary of protocol

Not provided at time of registration

# Contact information

#### Type(s)

Scientific

#### Contact name

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#### Contact details

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# Additional identifiers

Protocol serial number CSTI571BDE55

# Study information

Scientific Title

#### **Acronym**

GlivecGG

#### **Study objectives**

The aim is to assess the pharmacokinetics and efficacy of imatinib in patients with bile duct cancer and to test Positron Emission Tomography (PET) as a diagnostic tool.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Approved by the Local Ethics Committee of Leipzig University on 28 November 2005.

#### Study design

Non-randomised open label multicentre study

#### Primary study design

Interventional

#### Study type(s)

Treatment

#### Health condition(s) or problem(s) studied

Non-resectable bile duct cancer

#### **Interventions**

- 1. Continuous second line chemotherapy with imatinib assessment of response by tumor marker and imaging during follow-up
- 2. Generation of pharmacokinetic data during the first two days of drug administration and during the following weeks
- 3. Assessment of the efficacy of PET for evaluation of early treatment response

Added 01/09/09: trial was stopped prematurely due to a lack of a sufficient number of patients (9 in three and a half years).

#### Intervention Type

Drug

#### Phase

**Not Specified** 

#### Drug/device/biological/vaccine name(s)

Imitanib (Glivec)

#### Primary outcome(s)

- 1. Response rate
- 2. Median duration of objective remission

#### Key secondary outcome(s))

- 1. Time to progression
- 2. Median survival
- 3. Tumor response after one week or three months by 18-fluorodeoxyglucose-Positron Emission Tomography (18 FDG-PET)
- 4. Toxicity
- 5. Pharmacokinetics

#### Completion date

28/02/2010

#### Reason abandoned (if study stopped)

Participant recruitment issue

# **Eligibility**

#### Key inclusion criteria

- 1. Two-dimensional detectable tumors or metastasis
- 2. Aged between 18 and 75 years
- 3. General condition World Health Organisation (WHO) <2
- 4. Live expectancy of at least three months
- 5. Informed consent
- 6. Bilirubin not to be elevated more than upper normal value (1.5 times in the presence of liver metastasis) and alanine aminotransferase (ALT) or aspartate aminotransferase (AST) more than
- 1.5 times (2.5 times in the presence of liver metastasis) of the upper normal value
- 7. Creatinine <133 µmol/l (<1.5 mg/l), creatinine clearance >60 ml/min

#### Participant type(s)

Patient

### Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

#### Sex

All

#### Key exclusion criteria

- 1. Pregnant and lactating women, fertile men and women without adequate contraception
- 2. Patients that have not received primary chemotherapy
- 3. Pre-operated tumor recurrence
- 4. Tumor extent >50% of the liver or >25% of the lung, abdominal mass >10 cm, Central Nervous System (CNS) metastasis
- 5. Ileus
- 6. Non-measurable tumor

- 7. Known intolerance to imatinib and its preservatives
- 8. Second malignancy
- 9. Second unstable disease
- 10. Co-medication with non-approved drugs
- 11. Any other anti-cancer treatment
- 12. Co-medication with paracetamol

#### Date of first enrolment

01/03/2006

#### Date of final enrolment

28/02/2010

# Locations

#### Countries of recruitment

Germany

# Study participating centre Philipp-Rosenthalstr. 27

Leipzig Germany 04103

# Sponsor information

#### Organisation

University of Leipzig (Germany)

#### **ROR**

https://ror.org/03s7gtk40

# Funder(s)

# Funder type

Industry

#### Funder Name

Novartis Pharma GmbH (Germany)

#### Funder Name

Business Unit Oncology (Geschäftseinheit Onkologie) (Germany)

# **Results and Publications**

Individual participant data (IPD) sharing plan

#### IPD sharing plan summary

Not provided at time of registration

#### **Study outputs**

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet 11/11/2025 No Yes