ISRCTN32669229 https://doi.org/10.1186/ISRCTN32669229

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

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

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Dr Marcus Wiedmann

**Contact details**
Philipp-Rosenthalstr. 27
Leipzig
Germany
04103
+49 (0)34 1971 2230
wiedm@medizin.uni-leipzig.de

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
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

## Secondary study design
Non randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

## 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 measure
1. Response rate
2. Median duration of objective remission

### Secondary outcome measures
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

### Overall study start date
01/03/2006

### 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

### Age group
Adult

### Lower age limit

18 Years

### Sex
Both

### Target number of participants
40 - recruitment closed on 31/08/09 (9 recruited).

### 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)

### Sponsor details
Ritterstr. 26
Leipzig
Germany
04109
wiedm@medizin.uni-leipzig.de

### Sponsor type
University/education

### 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

### 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