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

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

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

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