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A phase II study to investigate the effect of Glivec® (imatinib mesylate, formerly known as STI571) in patients with inoperable medullary thyroid carcinoma

Submission date
23/02/2007

Recruitment status
No longer recruiting

Registration date
23/02/2007

Overall study status
Completed

Last Edited
20/12/2007

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
CSTI571BNL07; METC 03-044

Study information

Scientific Title

Study objectives
In the pathogenesis of medullary thyroid carcinoma a mutation of the rearranged during transfection (RET) tyrosine kinase system plays an essential role. In animal models the tyrosine kinase inhibitor imatinib showed tumor regression. So a phase II study in patients with progressive medullary thyroid carcinoma with imatinib may open new treatment possibilities.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Primary study design
Observational

Study design
Observational phase II study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Medullary thyroid carcinoma

Interventions
Oral treatment with 600 - 800 mg imatinib daily.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Imatinib mesylate (Glivec®)

Primary outcome(s)
The primary objective is to determine the objective response rate (partial and complete responses) in subjects with advanced medullary thyroid carcinoma.

Key secondary outcome(s)
1. To determine the time to tumour progression
2. To evaluate overall survival
3. To evaluate the safety profile of Glivec® in advanced medullary thyroid carcinoma

Completion date
11/07/2006

Eligibility

Key inclusion criteria
1. Patients over 18 years of age
2. The subject has advanced histologically proven medullary thyroid cancer. Advanced disease is defined as locally recurrent disease or metastatic disease that is not amenable to curative resection. The subject must have measurable disease.
3. The subject has not received anti-tumor radiotherapy or chemotherapy therapy within four weeks (six weeks for nitrosourea, mitomycin-C or any antibody therapy) of the start of imatinib administration
4. The subject has an Eastern Cooperative Oncology Group (ECOG) performance score of zero to two
5. Adequate end organ function, defined as the following:
5.1. Total bilirubin less than or equal to 1.5 x upper limit of normal (ULN)
5.2. Serum glutamic oxaloacetic transaminase (SGOT) and serum glutamic pyruvic transaminase (SGPT) less than 2.5 x ULN
5.3. Creatinine less than 1.5 x ULN
5.4. Absolute neutrophil count (ANC) more than 1.5 x 10^9/L
5.5. Platelets more than 100 x 10^9/L
6. Female patients of childbearing potential must have negative pregnancy test within seven days before initiation of study drug dosing. Postmenopausal women must be amenorrhoeic for at least 12 months to be considered of non-childbearing potential. Male and female patients of reproductive potential must agree to employ an effective barrier method of birth control throughout the study and for up to three months following discontinuation of study drug.
7. Life expectancy of more than three months (in the absence of any intervention)
8. The subject has voluntarily signed an Institutional Review Board (IRB)/Independent Ethics Committee (IEC) approved informed consent prior to any study specific procedures

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. The subject is less than five years free of another primary malignancy except:
1.1. If the other primary malignancy is not currently clinically significant nor requiring active intervention, or
1.2. If the other primary malignancy is a basal cell skin cancer or a cervical carcinoma in situ
2. The subject is with known brain metastases
3. The subject has received any other investigational agents within 28 days of first day of study

drug dosing
4. The subject has a current history of a class three to four cardiovascular disability status in accordance with the New York Heart Association Functional Classification:
4.1. Class three is defined as marked limitation of physical activity, comfortable at rest, but less than ordinary activity causes fatigue or dyspnea
4.2. Class four is defined as being unable to carry on any physical activity without symptoms and symptoms are present even at rest. Also, if any physical activity is undertaken, symptoms are increased
5. Female patients who are pregnant or breast-feeding
6. Patient has another severe and/or life-threatening medical disease
7. The subject has an acute or known chronic liver disease (e.g., chronic active hepatitis, cirrhosis)
8. The subject has a known diagnosis of human immunodeficiency virus (HIV) infection
9. The subject has received chemotherapy within four weeks (six weeks for nitrosourea, mitomycin-C or any antibody therapy) prior to study entry
10. The subject had a major surgery within two weeks prior to study entry
11. The subject uses therapeutic anticoagulation with warfarins. Low-molecular weight heparin (e.g. Fragmin®) or heparin is permitted.
12. The subject with any significant history of non-compliance to medical regimens or with inability to grant reliable informed consent

Date of first enrolment
11/07/2003

Date of final enrolment
11/07/2006

Locations

Countries of recruitment
Netherlands

Study participating centre
University Medical Centre Utrecht (UMCU)
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Sponsor information

Organisation
University Medical Centre Utrecht (UMCU) (The Netherlands)

ROR
https://ror.org/04pp8hn57

Funder(s)

Funder type
Industry

Funder Name
Novartis Pharma B.V. (The Netherlands)

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?
Results article	Results	01/09/2007		Yes	No