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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21527

Source
Nationaal Trial Register

Brief title
N/A

Health condition

Medullary thyroid carcinoma: progressive disease; phase-2 study, open label.

Sponsors and support

Primary sponsor: N/A
Source(s) of monetary or material Support: Novartis bv
Arnhem
The Netherlands

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

1. To determine the time to tumor progression;

2. To evaluate overall survival;

3. To evaluate the safety profile of Glivec in advanced medullary thyroid carcinoma.

Study description

Background summary

N/A

Study objective

In the pathogenesis of medullary thyroid carcinoma a mutation of the RET thyrosine kinase system plays an essential role. In animal models the thyrosine kinase inhibitor imatinib showed tumor regression. So a Phase-2 study in patients with progressive medullary thyroid carcinoma with imatinib may open new treatment possibilities.

Study design

N/A

Intervention

Oral treatment with 600-800 mg imatinib daily.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients „d 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 4 weeks (6 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 0-2 (as described in Section 5.3.1.1);

5. Adequate end organ function, defined as the following:
total bilirubin < 1.5 x ULN, SGOT and SGPT < 2.5 x UNL, creatinine < 1.5 x ULN, ANC > 1.5 x 109/L, platelets > 100 x 109/L;

6. Female patients of childbearing potential must have negative pregnancy test within 7 days before initiation of study drug dosing. Postmenopausal women must be amenorrheic 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 3 months following discontinuation of study drug;

7. Life expectancy of more than 3 months, (in the absence of any intervention);

8. The subject has voluntarily signed an IRB/IEC approved informed consent prior to any

study specific procedures.

Exclusion criteria

1. The subject is < 5 years free of another primary malignancy except: if the other primary malignancy is not currently clinically significant nor requiring active intervention, or if the other primary malignancy is a basal cell skin cancer or a cervical carcinoma in situ;

2. The subject 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 3-4 cardiovascular disability status in accordance with the New York Heart Association Functional Classification.

a. Class 3 is defined as marked limitation of physical activity, comfortable at rest, but less than ordinary activity causes fatigue or dyspnea.

b. Class 4 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 4 weeks (6 weeks for nitrosourea, mitomycin-C or any antibody therapy) prior to study entry;

10. The subject had a major surgery within 2 weeks prior to study entry;

11. The subject uses therapeutic anticoagulation with warfarines. 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.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-07-2003
Enrollment:	15
Type:	Actual

Ethics review

Positive opinion

Date:	12-09-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL329
NTR-old	NTR367
Other	: CSTI571BNL07 / METC 03-044
ISRCTN	ISRCTN13256080

Study results

Summary results

de Groot JW, Zonnenberg BA, van Ufford-Mannesse PQ, de Vries MM, Links TP, Lips CJ, Voest EE.A phase II trial of imatinib therapy for metastatic medullary thyroid carcinoma.J Clin Endocrinol Metab. 2007 Sep;92(9):3466-9.