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

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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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21527

Bron
Nationaal Trial Register

Verkorte titel
N/A

Aandoening

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

Ondersteuning

Primaire sponsor: N/A
Overige ondersteuning: Novartis bv
Arnhem
The Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

N/A

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Oral treatment with 600-800 mg imatinib daily.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Blindering:	Open / niet geblindeerd
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	11-07-2003
Aantal proefpersonen:	15
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	12-09-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

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.