Glivec (imatinib mesylate) in systemic sclerosis, a pilot study.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23406

Source
NTR

Brief title
N/A

Health condition

Systemic sclerosis, Glivec (imatinib mesylate)

Sponsors and support

Primary sponsor: Erasmus Medical Center
Source(s) of monetary or material Support: Novartis

Intervention

Outcome measures

Primary outcome

Primary efficacy variable:

· Rodnan skin score

Secondary outcome

Secondary efficacy variable:

· Disease severity score

· Number of digital ulcers

· Pulmonary function test (CO-diffusion)

· Kidney function as measured by creatinin clearance

Study description

Background summary

Design: an open label, investigator initiated study

Subjects: patients with systemic sclerosis (either diffuse or limited) refractory to standard therapy

Study medication: Glivec (imatinib mesylate) 400 mg daily, orally, during 12 months

Clinical Phase: Phase II (pilot study)

Objectives:
To investigate the efficacy (and the toxicity) of Glivec in systemic sclerosis by examining clinical outcomes (clinical and laboratory findings).

Primary efficacy variable:

· Rodnan skin score

Secondary efficacy variables:

· Disease severity score

· Number of digital ulcers

· Pulmonary function test (CO-diffusion)

· Kidney function as measured by creatinin clearance

Study objective

It is assumed that treatment with Imatinib mesylate will inhibit fibroblast proliferation in systemic sclerosis thereby leading to an improvement in clinical condition in patients.

Study design

December 2008 - recruitment

First patient in: December 2008

Last patient out: April 2010

Intervention

Glivec (imatinib mesylate) 400 mg daily, orally, during 12 months

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients with systemic sclerosis (either diffuse or limited) refractory to standard therapy

2. Adequate end organ function, defined as:

- total bilirubin <1.5 x ULN

- SGOT and SGPT < 2.5 x ULN (or <5 x ULN if hepatic disease involvement is present)

- creatinine < 1.5 x ULN

- ANC >1.5 x 109/L

- platelets > 100 x 109/L.

3. Adequate anticonception in women

4. Written informed consent

Exclusion criteria

1. Age < 18 years

2. Previous or current malignancy

3. Current treatment with endothelin receptor antagonist

4. Current treatment with immunosup-pressive drugs

5. Life expectancy < 6 months

6. Pregnancy

7. Inability to adhere to the current protocol

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-12-2008
Enrollment:	10
Type:	Anticipated

Ethics review

Positive opinion

Date:	01-12-2008
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	NL1495
NTR-old	NTR1565
Other	Novartis : CSTI571ENL18
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A