Dubbel-blind, gerandomiseerd onderzoek naar nilotinib bij spondyloartritis.

No registrations found.

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

Summary

ID

NL-OMON28855

Source
NTR

Brief title
Nilotinib

Health condition

spondyloarthritis

Sponsors and support

Primary sponsor: AMC
Source(s) of monetary or material Support: nvt

Intervention

Outcome measures

Primary outcome

1. Patient global assessment of disease activity VAS at week 12;

2. Physician global assessment of disease activity VAS at week 12;

3. Safety and tolerability over 24 weeks.

Secondary outcome

1. Patient global assessment of disease activity VAS at week 24;

2. Physician global assessment of disease activity VAS at week 24;

3. ASAS20 response at week 12 and 24;

4. ASDAS response at week 12 and 24.

Study description

Background summary

Country of recruitment: The Netherlands.

Study objective

Recently is an altered synovial fibroblast phenotype in SpA versus RA synovium revealed and currently is the role of PDGF in this process confirmed. PDGF-R, c-kit, and c-Fms are all tyrosine kinase receptors which can be blocked by tyrosine kinase inhibitors such as imatinib and nilotinib.

Study design

Visit 0 = screening (-28 to -1 days);

Visit 1 = week 0;

Visit 2 = week 2;

Visit 3 = week 4;

Visit 4 = week 6;

Visit 5 = week 8;

Visit 6 = week 12;

Visit 7 = week 14;

Visit 8 = week 16;

Visit 9 = week 18;

Visit 10 = week 20;

Visit 11 = week 24.

Intervention

1. Nilotinib (Tasigna ®) or matching placebo capsules (50% chance);

2. Athroscopy when arthritis.

Patients will receive 400 mg Nilotinib twice a day. After three months, all patients will receive this dose (open label phase).

Contacts

Public
AMC afd Kir
Meibergdreef 9
D.L. Baeten
Amsterdam 1105 AZ
The Netherlands
+31 (0)20 5667765
Scientific
AMC afd Kir
Meibergdreef 9
D.L. Baeten
Amsterdam 1105 AZ
The Netherlands
+31 (0)20 5667765

Eligibility criteria

Inclusion criteria

1. Patients should be able and willing to give written informed consent and comply with the requirements of the study protocol;

2. Patients should be between 18 and 65 years of age;

3. Patients must have a diagnosis of spondyloarthritis according to the ESSG criteria;

4. The patient must have an active disease as defined by a patient global assessment of disease activity VAS of > 4 AND a physician global assessment of disease activity VAS of > 4 AND > 1 swollen and > 1 tender joints in case of peripheral disease AND/OR a BASDAI of > 4 in case of axial disease;

5. Patients should have an inadequate response to at least one NSAID at the maximal tolerated dose;

6. The use of concomitant NSAIDs and corticosteroids is allowed. The dose of corticosteroids should not exceed a prednisone equivalent ≤ 10 mg/day and must
be stable for at least 4 weeks prior to baseline. The dose of concomitant NSAIDs and corticosteroids should be kept stable during the whole study period;

7. The use of concomitant DMARDs (methotrexate, sulphasalazine, or leflunomide) is allowed. If using DMARDs, patients must have received a minimum of 3 months of therapy and be on a stable dose for at least 4 weeks prior to baseline. The DMARDs should be kept stable during the study period;

8. Patients of reproductive potential (males and females) must use reliable methods of contraception (e.g. contraceptive pill, IUD, physical barrier) during the whole
study until 150 days post-study;

9. Patients are considered to be in generally good health based upon the result of a medical history, physical examination, laboratory profile, chest X-ray and ECG. In case of use of co-medication which can cause QT-prolongation, extra caution will be made.

Exclusion criteria

1. Patient has a significant comorbidity, including a cardiac, renal, hepatic, neurological, metabolic or any other disease, including ECG alterations, hypokalemia, and hypomagnesemia, that may affect his/her participation in this study;

2. Patient has a recent history of (or persistent) infection requiring hospitalization or antibiotic treatment within 4 weeks of baseline;

3. Patient has active tuberculosis. A PPD test and chest X-ray at screening should be negative (in case of latent tuberculosis, a patient may enter the study if prophylaxis with isoniazide is begun prior to administration of nilotinib). If a patient has an adequately treated active tuberculosis in the past he/she may enter the trial;

4. Patient has previously failed anti-TNF therapy or any other biological agent;

5. Patient has received an intra-articular injection with corticosteroids within 4 weeks prior to

baseline;

6. Patient has an active articular disease other than spondyloarthritis that could interfere with the assessment of spondyloarthritis;

7. Patient has an active or recent malignancy (other than basal cell carcinoma of the skin);

8. If female, patient should not be pregnant or breast-feeding. A urine pregnancy-test will be performed at screening and has to be negative;

9. Patient uses concomitant medication which inhibit or induce CYP3A4, such as ketoconazole, itraconazole, voriconazole, ritonavir, clarithromycin, telithromycin, rifampicin, phenytoin, carbamazepine, phenobarbital and St. John's Wort;

10. Patient is, in the opinion of the investigator, unable to comply with the requirements of the study protocol or is unsuitable for the study for any reason.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2011
Enrollment:	30
Type:	Actual

Ethics review

Positive opinion

Date:	31-03-2011
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	NL2305
NTR-old	NTR2834
Other	MEC AMC : 10/305
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A