Proof-of-concept double-blind, placebo-controlled, randomized clinical trial with nilotinib in spondyloarthritis

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To evaluate the efficacy and safety of nilotinib in spondyloarthritis

Ethical review	Approved WMO
Status	Pending
Health condition type	Autoimmune disorders
Study type	Interventional

Summary

ID

NL-OMON36414

Source
ToetsingOnline

Brief title
Nilotinib in spondyloarthritis

Condition

- Autoimmune disorders
- Joint disorders

Synonym
ankylosing spondylitis, spondyloarthropathy

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: collectebusfondsen,Novartis

Intervention

Keyword: Nilotinib, Spondyloarthritis, Treatment, Tyrosine kinase inhibitor

Outcome measures

Primary outcome

- Patient global assessment of disease activity VAS at week 12

- Physician global assessment of disease activity VAS at week 12

- Safety and tolerability over 24 weeks

Secondary outcome

- Patient global assessment of disease activity VAS at week 24

- Physician global assessment of disease activity VAS at week 24

- ASAS20 response at week 12 and week 24

- ASDAS response at week 12 and week 24

- Change in BASDAI at week 12 and week 24

- ESR and CRP at week 12 and 24

- Change in SJC and TJC at week 12 and week 24

- Soluble biomarkers at week 12 and week 24

- Synovial tissue response at week 12 and week 24

Study description

Background summary

Spondyloarthritis (SpA) is the second most frequent form of chronic inflammatory arthritis with a prevalence of 0.5%. It affects mainly young adults and leads to major functional handicap due to inflammation of axial and peripheral joints as well as progressive ankylosis and structural damage. However standard therapy is not always successful. It has been shown in basic research and also a small clinical trial in humans that tyrosine kinase

inhibitor might have a beneficial effect in patient with spondyloarthritis.

Study objective

To evaluate the efficacy and safety of nilotinib in spondyloarthritis

Study design

proof-of-concept randomized, placebo controlled, clinical trial

Intervention

- study medication (capsules 2 dd 2 capsules)
- mini-arthroscopie 3 times if arthritis of knee or ankle
- Chest X-ray, PPD-skin test, ECG at screening
- venapunctures
- urine sample
- general internal and rheumatological physical exam
- questionaires

Study burden and risks

12 study visitis, the risk of adverse events of the study medication and the risk of complication related to the mini-arthroscopy if applicable

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Active peripheral or axial spondyloarthritis according to ESSG criteria
- Age between 18-65 years

Exclusion criteria

- Significant comorbidity
- Failure on anti-TNF-therapy
- Unstable dose of DMARDs or corticosteroids

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL
Recruitment status: Pending

Start date (anticipated):	01-02-2011
Enrollment:	30
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Tasigna
Generic name:	Nilotinib
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	21-04-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
EudraCT	EUCTR2010-023185-42-NL
CCMO	NL34748.018.10