A randomised, double-blind, placebo-controlled, proof-of-concept, dose-ranging study of BI 655066 in patients with active psoriatic arthritis

Published: 11-02-2016
Last updated: 17-04-2024

Voor meer informatie verwijs ik u naar sectie 2 in het protocol

Ethical review	Approved WMO
Status	Will not start
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON44526

Source
ToetsingOnline

Brief title
1311.5

Condition

- Joint disorders

Synonym
active psoriatic arthritis, form of arthritis with psoriasis

Research involving
Human

Sponsors and support

Primary sponsor: Boehringer Ingelheim
Source(s) of monetary or material Support: Boehringer Ingelheim BV

Intervention

Keyword: active psoriatic arthritis, BI 655066, monoclonal antibody, proof of concept

Outcome measures

Primary outcome

Voor meer informatie verwijs ik u naar sectie 5 in het protocol

Secondary outcome

Voor meer informatie verwijs ik u naar sectie 5 in het protocol

Study description

Background summary

Voor meer informatie verwijs ik u naar sectie 1 in het protocol

Study objective

Voor meer informatie verwijs ik u naar sectie 2 in het protocol

Study design

Voor meer informatie verwijs ik u naar sectie 3 in het protocol

Intervention

Voor meer informatie verwijs ik u naar sectie 4.1.4 in het protocol

Study burden and risks

Voor meer informatie verwijs ik u naar sectie 5.2 in het protocol
+ de flowchart op pagina 5 t/m 7

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

- Have PsA symptoms for >/= 6 months prior to screening, as assessed by the investigator;- Have PsA on the basis of the Classification Criteria for Psoriatic Arthritis (CASPAR) with peripheral symptoms at screening visit, as assessed by the investigator;- Have >/= 5 tender joints and >/= 5 swollen joints at screening and randomisation visits, as assessed by the investigator;- At least one PsO lesion or a documented personal history of PsO at screening, as assessed by the investigator;- If patients receive concurrent PsA treatments, these need to be on stable doses;- Active PsA that has been inadequately controlled by standard doses of NSAIDs administered for >/= 4 weeks, or traditional DMARDs (including sulfasalazine) administered for >/= 3 months, or TNFi agents, or subjects are intolerant to NSAIDs or DMARDs or TNFi agents, as assessed by the investigator;- Signed and dated written informed consent prior to admission to the study in accordance with GCP and local legislation;- Further inclusion criteria apply

Exclusion criteria

- Major chronic inflammatory or connective tissue disease other than PsA (e.g. rheumatoid arthritis, systemic lupus erythematosus, ankylosing spondylitis, Lyme disease, gout) and

fibromyalgia, as assessed by the investigator;- Has received any therapeutic agent directly targeted to IL-12/23 (including ustekinumab), IL-23 or IL-17 (including secukinumab);- Prior use of more than two different TNFi agents;- Use of the following treatments: TNFi agents within 12 weeks, etanercept within 8 weeks, leflunomide without cholestyramine wash-out within 8 weeks, systemic non-biologic medications for psoriatic arthritis or psoriasis and photochemotherapy within 4 weeks, intraarticular injections (including steroids) and intramuscular or intravenous corticosteroid treatment within 4 weeks, topical psoriasis medications and phototherapy within 2 weeks, low and high potency opioid analgesics within 2 weeks prior to randomisation;- Plans for administration of live vaccines during the study period or within 6 weeks prior to randomisation;- History of allergy/hypersensitivity to a systemically administered biologic agent or its excipients;- Active systemic infections during the last 2 weeks (exception: common cold) prior to randomisation, as assessed by the investigator;- Chronic or relevant acute infections including HIV, viral hepatitis and (or) active tuberculosis. Patients with a positive QuantiFERON TB or PPD test may participate in the study if further work up (according to local practice/guidelines) establishes conclusively that the patient has no evidence of active tuberculosis. If presence of latent tuberculosis is established, then tuberculosis treatment may be deferred until completion of the trial according to clinical judgment of investigator and local country guidelines.;- Any documented active or suspected malignancy or history of malignancy within 5 years prior to screening, except appropriately treated basal or squamous cell carcinoma of the skin or in situ carcinoma of uterine cervix;- Major surgery performed within 12 weeks prior to randomisation or planned within 32 weeks after randomisation (e.g. hip replacement, aneurysm removal, stomach ligation), as assessed by the investigator;- Total white blood count (WBC) < 3,000/µL, or platelets < 100,000/µL or neutrophils < 1,500/µL, or hemoglobin <8.5 g/dL at screening;- Aspartate aminotransferase (AST) or alanine aminotransferase (ALT) > 2x the upper limit of normal, or serum direct bilirubin = 1.5 mg/dL at screening;- Positive rheumatoid factor or anti-cyclic-citrullinated peptide (anti-CCP) antibodies at screening;- Further exclusion criteria apply

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:	Will not start
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Unknown
Generic name:	Unknown

Ethics review

Approved WMO Date:	11-02-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-05-2016
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	EUCTR2015-003625-34-NL
CCMO	NL56654.018.16