A multicenter, open-label (Part A) followed by a randomized, double-blind, parallel-group, placebo controlled study (Part B) to evaluate maintenance of remission in subjects with active axial spondyloarthritis (axSpA) receiving either Certolizumab pegol 200mg Q2W or 200mg Q4W as compared to placebo

Published: 05-08-2015
Last updated: 20-04-2024

The primary objective of the study is to evaluate the percentage of subjects who do not experience a flare on CZP 200mg Q2W (full-dose) or 200mg Q4W (half-dose) during Part B. The secondary objectives are: 1) to evaluate the percentage of subjects…

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

Summary

ID

NL-OMON44938

Source
ToetsingOnline

Brief title
AS0005 (C-Optimise)

Condition

- Autoimmune disorders
- Joint disorders

Synonym
inflammation, reumathism

Research involving
Human

Sponsors and support

Primary sponsor: UCB Biosciences GmbH
Source(s) of monetary or material Support: UCB

Intervention

Keyword: axial spondyloarthritis (axSpA), placebo, remission

Outcome measures

Primary outcome

The primary efficacy variable is the percentage of subjects in Part B who do not experience a flare (refer to Section 3 for definition of flare). Secondary efficacy variables for subjects entering Part A are: 1) percentage of subjects achieving sustained remission at Week 48 and
2) Ankylosing Spondylitis Disease Activity Score (ASDAS) disease activity and clinical improvement at Week 48.

Secondary outcome

The following are secondary efficacy variables for subjects entering Part B: 1) time to flare,
2) ASDAS disease activity and clinical improvement at Week 96, 3) assessment in Axial SpondyloArthritis International Society (ASAS) response criteria (ASAS20, ASAS40, ASAS 5 out of 6 [ASAS 5/6], and ASAS partial remission [PR] responses) at Week 96, 4) change from Baseline in: ASDAS, Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), Bath Ankylosing Spondylitis Functional Index

(BASFI), and Bath Ankylosing Spondylitis Metrology Index (BASMI) at Week 96, 5) BASDAI50 response, and 6) change from Baseline in Sacroiliac SpondyloArthritis Research Consortium of Canada (SPARCC) and ankylosing spondylitis spine MRI score for activity (ASspIMRI-a) in the Berlin modification scores at Week 96.

The following are secondary efficacy variables for subjects who experience a flare in Part B. These will be evaluated at Week 96 or a later timepoint, if applicable: 1) ASDAS disease activity and clinical improvement, 2) ASAS20, ASAS40, ASAS5/6, and ASAS PR response, and
3) Change from Baseline in ASDAS, BASDAI, BASFI, BASMI, and MRI.

Study description

Background summary

Axial Spondyloarthritis (axSpA) is a chronic inflammatory disease. This is a type of rheumatic disorders that impacts a substantial proportion of the population. The majority of patients with axSpA have back pain due to inflammation. The most characteristic feature of axSpA is the formation of new bone that ultimately leads to a fusion of the spine. Axial SpA typically presents in patients younger than 45 years of age. Unfortunately, many patients are diagnosed in a late stage of this disease when fusion of the sacroiliac joints (where your lower back meets with your pelvis) and maybe even the spine has already progressed significantly. In this study patients with an early disease stage (axSpA) and progressed stage (AS * Ankylosing Spondylitis) will be treated with an anti-inflammatory drug named Certolizumab pegol, with the aim to achieve a significant improvement of the health status of axSpA and AS patients and to demonstrate that the improved health status can be maintained after reduction or even withdrawal of the study drug.

Study objective

The primary objective of the study is to evaluate the percentage of subjects who do not experience a flare on CZP 200mg Q2W (full-dose) or 200mg Q4W (half-dose) during Part B. The secondary objectives are: 1) to evaluate the

percentage of subjects achieving sustained remission at the end of Part A, 2) to evaluate the time to flare and other measures of signs and symptoms, to compare the percentage of subjects who do not experience a flare between CZP full-dose and half-dose, and to evaluate the efficacy of re-initiation of treatment with the CZP full-dose in subjects who experience a flare following a withdrawal or dose reduction of CZP for subjects randomized into Part B, 3) to assess safety and tolerability of CZP, and 4) to evaluate inflammatory changes over time as assessed by magnetic resonance imaging (MRI).

Study design

Study AS0005 is a multicenter, open-label (Part A) followed by a randomized, double-blind, parallel-group, placebo-controlled clinical study (Part B) to evaluate the efficacy, safety, pharmacokinetics (PK), and immunogenicity of certolizumab pegol (CZP) in adult subjects with active axial spondyloarthritis (axSpA) in sustained remission who continued either on full-dose treatment (CZP 200mg every 2 weeks [Q2W]), on a dose reduction (CZP 200mg every 4 weeks [Q4W]) or withdrawal of CZP treatment. The study includes 2 parts: an Open-Label Run-In Period for 48 weeks (Part A) followed by a Double-Blind Period for 48 weeks (Part B) with
3 treatment arms (200mg CZP Q2W [referred to as full-dose], 200mg CZP Q4W [referred to as half-dose], and placebo), and a Safety Follow-Up (SFU) Period for 10 weeks after the last dose of study medication.

Intervention

Eligible subjects will receive
3 loading doses of CZP 400mg subcutaneous (sc) at Weeks 0 (Baseline), 2, and 4 followed by CZP 200mg Q2W in Period 2 from Week 6 to Week 46.
Subjects in sustained remission at the end of Part A will be randomized in a 1:1:1 ratio to the following treatment arms: 1) CZP administered sc at a dose of 200mg Q2W (full-dose), 2) CZP administered sc at a dose of 200mg Q4W (half-dose), and 3) placebo.

Study burden and risks

For the patient the extra burden is mostly the tests to keep checking the health, and the question lists also for health and wellbeing.
Also because of this the patient will be monitored well for possible side effects of the medication and/or procedures (injections).
the results of this study will be important for the treatment of this type of patients.

Contacts

Public
UCB Biosciences GmbH

Alfred Nobel Strasse 10
Monheim 40789
DE
Scientific
UCB Biosciences GmbH

Alfred Nobel Strasse 10
Monheim 40789
DE

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- At least 18 years old and not older than 45
- A documented diagnosis of adult-onset axSpA with at least 3 months' symptom duration
- Active disease at Screening
- An inadequate response to, have a contraindication to, or have been intolerant to at least 2 NSAIDs

Exclusion criteria

AxSpA disease-related exclusions:
- must not have fibromyalgia or total spinal ankylosis ("bamboo spine"), or any other inflammatory arthritis, eg, RA, systemic lupus erythematosus, sarcoidosis.

- must not have a secondary, noninflammatory condition (eg, osteoarthritis) that in the Investigator's opinion is symptomatic enough to interfere with evaluation of the effect of study medication on the subject's primary diagnosis of axSpA.;- Also must not have used a range of medications, or biological therapies, or vaccines
- known TB infection, at high risk of acquiring TB infection, or LTB infection
- not in a good condition according several parameters

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-01-2016
Enrollment:	8
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Cimzia
Generic name:	certolizumab pegol
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	placebo
Generic name:	placebo
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO
Date: 05-08-2015
Application type: First submission
Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Approved WMO
Date: 23-12-2015
Application type: First submission
Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Approved WMO
Date: 10-02-2016
Application type: Amendment
Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Approved WMO
Date: 19-02-2016
Application type: Amendment
Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Not approved
Date: 03-08-2016
Application type: Amendment
Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Approved WMO
Date: 18-11-2016
Application type: Amendment

Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	13-12-2016
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	11-10-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	01-11-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	EUCTR2015-000339-34-NL
ClinicalTrials.gov	NCT02505542
CCMO	NL54385.098.15

Study results

Date completed:	01-06-2018
Actual enrolment:	10