Inclusion Criteria

Patients had to meet all of the following criteria to qualify for study participation:

1. =Û8 years at the Screening visit.
2. A clear chest X-ray within 3 months prior to the Baseline visit.
3. Female patients of childbearing potential must have had a negative serum pregnancy test at Screening and negative urine testing immediately before every investigational product administration. Females must have been surgically sterile, postmenopausal for at least 2 years prior to Screening, must have undergone tubal ligation or be using an acceptable method of birth control for the duration of the study and for 12 weeks after the last dose of CZP. Oral contraceptives must have been stable for at least 28 days prior to the screening visit. Abstinence was not an acceptable method of contraception for the study.
4. A diagnosis of adult-onset RA (of at least 6 months duration but not longer than 15 years prior to Screening) as defined by the 1987 ACR classification criteria.
5. Active RA disease at Screening and Baseline as defined by:
    - 9 tender joints
    - 9 swollen joints
    - And fulfillment of 1 of the following 2 criteria:

        a. =Ø0 mm/hour erythrocyte sedimentation rate (ESR) (Westergren), or

        b. C-reactive protein (CRP) >15 mg/L.
6. Received treatment with MTX (with or without folic acid) for at least 6 months prior to the Baseline visit. The dose of MTX had to have been stable for at least 2 months prior to the Baseline visit. The minimum dose of MTX had to be equivalent to 10 mg weekly.
7. Willing to attend Week 24 for X-ray of the hands and feet even if they were no longer receiving study treatment but had not withdrawn informed consent.
8. Able to understand the information provided to them and give written informed consent.

Exclusion Criteria

Patients who met any of the following criteria were to be excluded from study participation:

1. Diagnosis of any other inflammatory arthritis (e.g., psoriatic arthritis or ankylosing spondylitis).
2. A secondary, non-inflammatory type of arthritis (e.g., osteoarthritis or fibromyalgia) that in the Investigator's opinion was symptomatic enough to interfere with evaluation of the effect of CZP on the patient's primary diagnosis of RA.
3. History of an infected joint prosthesis at any time with prosthesis still *in situ*.

Concomitant medication exclusions

1. Did not meet any of the concomitant medication criteria listed in **Table 1**.

Table 1. Exclusion Based on Use of Concomitant Medications

Drug class	Dose	Exclusion Criteria
Analgesics	Any dose	In the 24 hours prior to the Baseline arthritis assessment.
NSAIDs/COX-2 inhibitors	Any dose regimen	Any change in dose regimen in the 14 days prior to Baseline Arthritis Assessment.
Oral corticosteroids	Maximum dose allowed not greater than 10 mg prednisone (or equivalent) per day	Any change in dose in the 28 days prior to the Baseline arthritis assessment.
IM/IV/IA corticosteroids	Any dose	In the 28 days prior to the Baseline arthritis assessment.
IA hyaluronic acid	Any dose	In the 28 days prior to the Baseline arthritis assessment.
DMARDS– sulfasalazine, azathioprine, cyclosporin, hydroxychloroquine, chloroquine, penicillamine, gold, cyclophosphamide.	Any dose	In the 28 days prior to the Baseline arthritis assessment.
DMARDs – leflunomide	Any dose	In the 6 months prior to the Baseline arthritis assessment unless a cholestyramine washout had been performed (according to local guidelines); in which case, 28 days prior to the Baseline arthritis assessment was acceptable.

Previous clinical trials and previous biological therapy exclusions

1. Received any experimental non-biological therapy, within or outside a clinical study in the 3 months prior to Baseline.
2. Received any biological therapy for RA within 6 months prior to Baseline, except for etanercept and anakinra where 3 months prior to Baseline was acceptable.
3. Previous treatment with a biological therapy for RA that resulted in a severe hypersensitivity reaction or, an anaphylactic reaction. Patients who previously had not responded to treatment with an anti-TNF drug were also excluded.
4. Were lactating and/or pregnant, or planned to become pregnant during the trial or within 3 months following the last dose of investigation product.

Medical History Exclusions

1. If female of childbearing potential, was not practicing effective birth control. All female patients had to have a negative serum pregnancy test before study entry and a negative urine pregnancy test immediately before every CZP administration.
2. History of chronic infection, recent serious or life-threatening infection (within 6 months, including herpes zoster), or any current sign or symptom that may have indicated an infection (e.g., fever, cough).
3. History of tuberculosis (TB) or positive chest X-ray for TB or positive purified protein derivatives (PPD) skin test (defined as positive induration per local medical practice). Patients with a positive PPD skin test associated with previous vaccination where there was no clinical or radiographic suspicion of TB could have been enrolled at the discretion of the Investigator. Consideration was given to the fact that a positive PPD skin test with prior vaccination dose did not exclude latent TB.
4. History of a lymphoproliferative disorder including lymphoma or signs and symptoms suggestive of lymphoproliferative disease at any time.
5. Were at a high risk of infection in the Investigator's opinion (e.g., patients with leg ulcers, indwelling urinary catheter, persistent or recurrent chest infections and patients who were permanently bed ridden or wheelchair bound).
6. Known positive hepatitis B surface antigen test and/or hepatitis C antibody test result.
7. Received any vaccination (live or attenuated) within 8 weeks prior to Baseline. (Influenza and Pneumococcal vaccines were allowed).
8. Active malignancy of any type or a history of malignancy (except basal cell carcinoma of the skin that had been excised prior to study start).
9. History of blood dyscrasias.
10. Current or recent history of severe, progressive, and/or uncontrolled renal, hepatic, hematological, GI, endocrine, pulmonary, cardiac, neurological, or cerebral disease.
11. Known human immunodeficiency virus infection.
12. New York Heart Association 1964 class III-IV congestive heart failure.
13. History of, or suspected, demyelinating disease of the central nervous system (e.g., multiple sclerosis or optic neuritis).
14. History of an adverse reaction to PEG or a protein medicinal product.
15. Any other condition, which in the Investigator's judgment made the patient unsuitable for inclusion in the study.