Supplementary Methods

Subjects could continue the following medications at a stable dosage: sulfasalazine (≤3 g/day), methotrexate (≤25 mg/week), prednisone or equivalent (≤10 mg/day), and NSAIDs. Washout periods of 10 weeks for adalimumab, golimumab, and certolizumab, 8 weeks for infliximab, and 4 weeks for etanercept were required before Baseline. Disease-modifying anti–rheumatic drugs other than sulfasalazine or methotrexate were discontinued 4 weeks prior to randomization (8 weeks for leflunomide, unless a cholestyramine washout was performed).

Key exclusion criteria included total spinal ankylosis, evidence of infection or malignancy on chest X-ray, active systemic infection within 2 weeks before Baseline visit, and previous treatment with cell-depleting therapies or biologics other than anti–TNF therapy.

The ASAS response measures consisted of the following assessment domains:

Main ASAS domains:

1. Patient's global assessment of disease activity measured on a VAS scale
2. Patient's assessment of back pain, represented by either total or nocturnal pain scores, both measured on a VAS scale
3. Function represented by BASFI average of 10 questions regarding ability to perform specific tasks as measured by VAS scale
4. Inflammation represented by mean duration and severity of morning stiffness, represented by the average of the last 2 questions on the 6-question BASDAI as measured by VAS scale

Additional assessment domains:

1. Spinal mobility represented by the BASMI lateral spinal flexion assessment
2. C reactive protein (acute phase reactant)

Secondary endpoints assessed at Week 16 included ASAS40 response (≥40% improvement in three of four main ASAS response criteria, with no worsening in the fourth); change from Baseline in high-sensitivity C-reactive protein (hsCRP); ASAS5/6 improvement (≥20% improvement in five of the six ASAS response criteria); changes from Baseline in total BASDAI

score (scores range from 0–10, with 0 representing no problem and 10 the worst problem), Medical Outcomes Study Short Form-36 Health Survey Physical Component Summary (SF-36 PCS v2; scores range from 0–100 for individual domains [0 representing maximum disability and 100 no disability], with a normative score of 50 for the composite Physical Component Summary), and AS Quality of Life (ASQoL; scores range from 0–18, with 0 representing lowest severity and 18 highest severity), and ASAS partial remission (a score of ≤2 units in each of the four core ASAS domains).

Between-treatment differences in continuous variables were evaluated using a mixed-effect model repeated-measures (MMRM; valid under the missing at random assumption), with treatment, analysis visit, and anti–TNF response status as factors. Weight and Baseline values were included in the model as continuous covariates. Interaction terms included treatment and Baseline value by analysis visit.