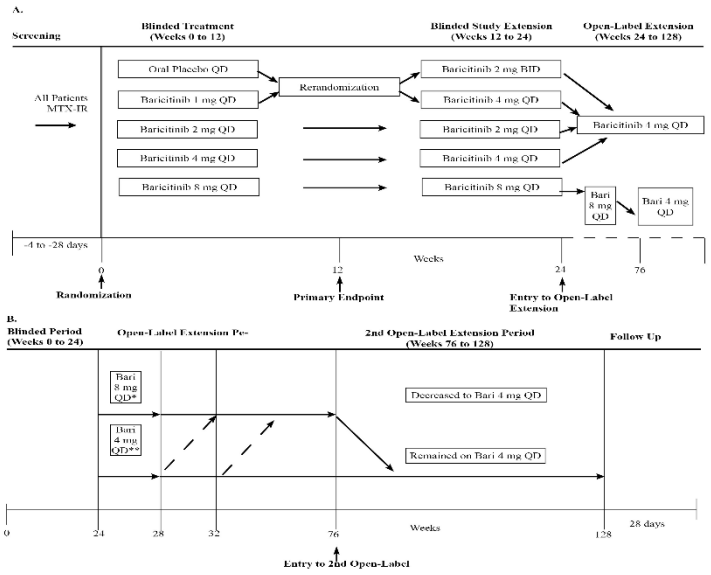
Online supplement to Safety and Efficacy of Baricitinib through 128 Weeks in an Open-label, Longterm Extension Study in Patients with Rheumatoid Arthritis, *The Journal of Rheumatology*, doi:10.3899/jrheum.161161

Supplementary Figure 1. Study design, weeks 0-128.



(A) Study design for blinded period (Weeks 0-24). Patients completing Week 24 are eligible to enter the first optional open-label extension (OLE). Patients not entering the OLE proceed to follow-up visit. (B) Study design for first OLE (Weeks 24-76) and second OLE (Weeks 76-128). Patients completing Week 76 are eligible to enter the second optional OLE. Patients not entering the OLE proceed to follow-up visit. Dashed arrow in (B) represents optional dose escalation at Weeks 28 and 32. Patients with ≥6 tender and ≥6 swollen joints were eligible for escalation. Solid arrow in (B) represents required dose reduction at Week 76.

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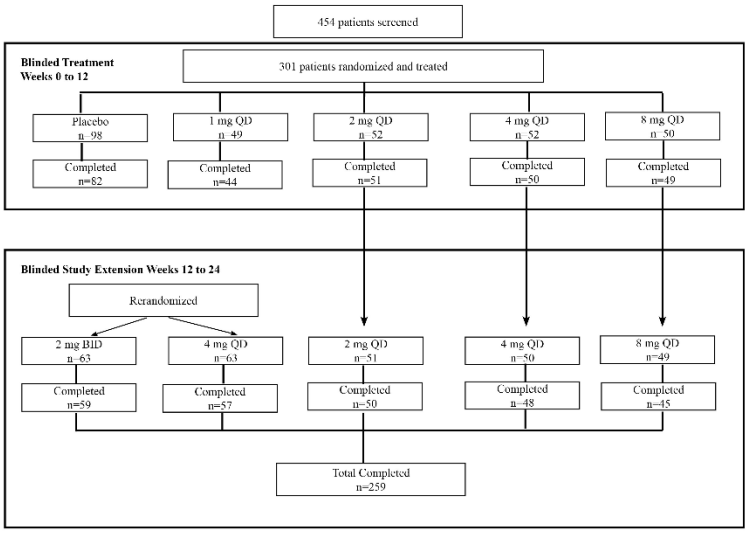
Supplementary Figure 2. Patient disposition, weeks 0-24.



BID: twice-daily; QD: once daily.

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Supplementary Table 1. Incidence of selected SAE, weeks 0-24, weeks 24-76, and weeks 76-128.

	Blinded Period Weeks 0-24			First OLE Weeks 24-76				Second OLE Weeks 76-128		
	Randomized dose				4:8 mg					
n (%)	2 mg N=5 2	4 mg N=5 2	8 mg N=5 0	4 mg N=10 8	Pre-RescueN=6 1	Post-RescueN=6 1	8 mg N=3 2	4/4 mg N=7 9	4:8/4 mg N=4 7	8/4 mg N=1 8
Blood and lymphatic system disorders	0	0	2 (4)	1 (1)	0	1 (2)	0	0	0	0
Anemia	0	0	1 (2)	1 (1)	0	0	0	0	0	0
Normochromic normocytic anemia	0	0	0	0	0	1 (2)	0	0	0	0
Pancytopenia	0	0	1 (2)	0	0	0	0	0	0	0
Cardiac disorders	0	0	0	0	0	0	1 (3)	0	0	0
Myocardial infarction	0	0	0	0	0	0	1 (3)	0	0	0
Eye disorders	0	0	0	2 (2)	0	0	1 (3)	0	0	0

Cataract	0	0	0	2 (2)	0	0	0	0	0	0
Ulcerative keratitis	0	0	0	0	0	0	1 (3)	0	0	0
Gastrointestinal disorders	0	0	1 (2)	0	0	2 (3)	1 (3)	1 (1)	0	0
General disorders	0	0	0	0	0	0	0	1 (1)	0	0
Hepatobiliary disorders	0	0	0	0	0	0	0	1 (1)	0	0
Cholelithiasis	0	0	0	0	0	0	0	1 (1)	0	0
Infections and infestations	2 (4)	0	1 (2)	5 (5)	1 (2)	1 (2)	2 (6)	2 (3)	2 (4)	0
Acute hepatitis B	0	0	0	0	0	0	1 (3)	0	0	0
Bronchitis	1 (2)	0	0	0	0	0	0	0	0	0
Gastroenteritis	0	0	0	1 (1)	0	0	0	0	1 (2)	0
Gastroenteritis, viral	0	0	0	0	1 (2)	0	0	0	0	0
Herpes simplex	0	0	0	0	0	1 (2)	0	1 (1)	0	0
Herpes zoster	0	0	0	4 (4)	0	0	1 (3)	1 (1)	0	0
Pneumonia	1 (2)	0	0	0	0	0	0	0	2 (4)	0
Pneumonia, bacterial	0	0	1 (2)	0	0	0	0	0	0	0

Injury, poisoning, and procedural complications	1 (2)	0	0	2 (2)	0	1 (2)	0	0	0	0
Investigations	0	0	0	4 (4)	0	0	0	0	0	0
ALT increased	0	0	0	2 (2)	0	0	0	0	0	0
AST increased	0	0	0	1 (1)	0	0	0	0	0	0
Blood CPK increased	0	0	0	1 (1)	0	0	0	0	0	0
Transaminases increased	0	0	0	1 (1)	0	0	0	0	0	0
Metabolism and nutrition disorders	0	0	0	1 (1)	0	0	1 (3)	0	1 (2)	0
Musculoskeletal and connective tissue disorders	0	0	0	2 (2)	0	1 (2)	0	2 (3)	0	0
Nervous system disorders	0	0	0	1 (1)	0	0	1 (3)	0	1 (2)	0
Pregnancy, puerperium,	0	0	0	0	0	1 (2)	0	0	0	0

and perinatal conditions										
Psychiatric disorders	0	0	0	0	0	0	0	0	1 (2)	0
Renal and urinary disorders	0	0	1 (2)	0	0	0	0	0	0	0
Renal failure	0	0	1 (2)	0	0	0	0	0	0	0
Respiratory, thoracic, and mediastinal disorders	1 (2)	0	0	0	0	1 (2)	0	0	0	0
Skin and subcutaneous tissue disorders	0	0	0	1 (1)	0	0	0	0	0	0

4/4 mg = 4 mg baricitinib for Weeks 24-76 and Weeks 76-128

4:8/4 = 4 mg baricitinib through Week 28 or 32 then 8 mg through Week 76 and 4 mg for Weeks 76-128. 8/4 mg = 8 mg baricitinib for Weeks 24-76 and 4 mg for Weeks 76-128

Pre-Rescue includes all SAEs that began on or before the date of dose escalation. Post-Rescue includes all SAEs that began after the date of dose escalation. SAEs coded using MedDRA version 16.1. *N* number of patients treated with stated dose regimen in the study period; *n* number of patients with event, OLE open-label extension, *SAE* serious adverse event.

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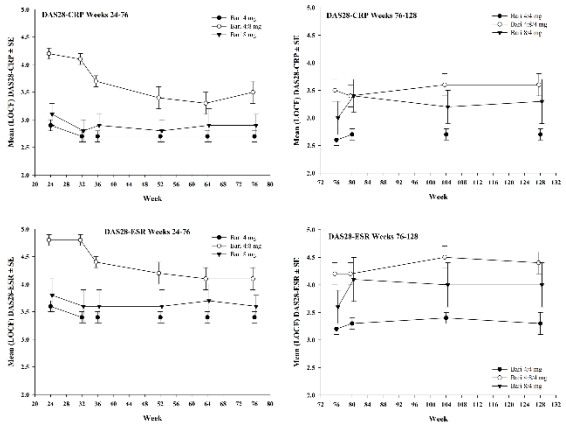
Supplementary Figure 3. Mean (LOCF) DAS28-CRP ± SE and DAS28-ESR ± SE for weeks 24-76 and weeks 76-128.



Bari baricitinib, CRP C-reactive protein, DAS28-CRP Disease Activity Score for 28-joint counts based on the CRP level, DAS28-ESR Disease Activity Score for 28-joint counts based on the ESR, ESR erythrocyte sedimentation rate, LOCF last observation carried forward, SE standard error.

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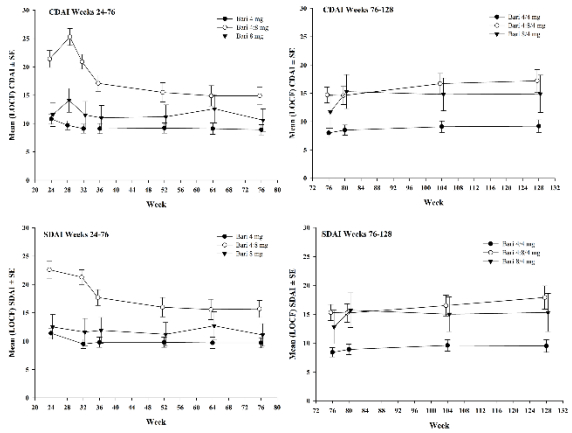
Supplementary Figure 4. Mean (LOCF) CDAI ± SE and SDAI ± SE for weeks 24-76 and weeks 76-128.



Bari baricitinib, CDAI Clinical Disease Activity Index, LOCF last observation carried forward, SDAI Simplified Disease Activity Index, SE standard error.