

Table 2. Summary of findings: comparison of abatacept (2 and 10 mg/kg) + DMARD/biologic versus placebo + DMARD/biologic for RA.

Outcomes	Illustrative Assumed Risk Placebo + DMARD/Biologic	Comparative Risks* (95% CI) Corresponding Risk Abatacept (2 and 10 mg/kg) + DMARD/Biologic	Relative Effect (95% CI)	No. of Participants (No. Studies)	Quality of Evidence (grade [†])	Comments (95% CI)
ACR 50% improvement Followup 12 mo	168 per 1000	371 per 1000 (291 to 474)	RR 2.21 (1.73 to 2.82)	993 (3)	+++– moderate ^{1,2,3}	Absolute risk difference 21% (16% to 27%). Relative change = 121% (73% to 182%). NNT = 5 (4 to 7) ⁴
Pain: measured at end of study on a 100 mm VAS from 0 (better) to 100 (worse) Followup 12 mo	Mean pain in control groups = 49.24 mm	Mean pain in intervention groups = 10.71 lower (12.97 to 8.45 lower)		1425 (1 ⁵)	+++– moderate ²	Absolute risk difference –11% (–13% to –8.5%). Relative change = –18% (–22% to –14%). NNT = 5 (4 to 6) ⁴
Improvement in physical function (HAQ: > 0.3 increase from baseline, 0–3 scale) Followup 12 mo	393 per 1000	637 per 1000 (531 to 766)	RR 1.62 (1.35 to 1.95)	638 (1 ⁶)	+++– moderate ¹	Absolute risk difference 24% (16% to 32%). Relative change = 62% (35% to 95%). NNT = 5 (4 to 7) ⁴
Achievement of low disease activity state (DAS 28 < 3.2, scale 1–10) Followup 12 mo	98 per 1000	424 per 1000 (278 to 646)	RR 4.33 (2.84 to 6.59)	638 (1 ⁶)	+++– moderate ¹	Absolute risk difference 33% (26% to 39%). Relative change = 333% (184% to 559%) NNT = 4 (3 to 5) ⁴
Total serious adverse events Followup 6 to 12 mo	121 per 1000	127 per 1000 (105 to 155)	RR 1.05 (0.87 to 1.28)	3151 (6)	+++– moderate ^{1,2,3,7}	Absolute risk difference 1% (–2% to 3%). Relative change = 5% (–14% to 29%). NNT = NA ⁴
Change in radiographic progression: measured by Genant-modified Sharp erosion score (increase in score means more joint damage). Scale 0 to 145 Followup 12 mo	Median change in radiographic progression in control group = 0.27 units	Median change in radiographic progression in intervention group = 0 units		586 (1 study ⁶)	+++– moderate ^{1,8}	Note there was no change in the abatacept group. MD –0.27 (–0.42, –0.12). Absolute risk difference = –0.2% (–0.3% to –0.08%). Relative change = –1.2% (–1.9% to –0.6%)
Longterm serious adverse events Followup 2 yrs	See comment	See comment	Not estimable	950 (2 ⁹)	++– – low ¹⁰	No. of patients with SAE: Genovese 2005 ²² : 103/357; 23.4 SAE/100 patient-yrs; 70% completed the LTE. Kremer 2006 ²⁴ : 149/593; 16.3 SAE/100 patient-yrs; 90.5% completed the LTE

* The basis for the assumed risk (e.g., the median control group risk across studies) is provided in footnotes. The corresponding risk (95% CI) is based on the assumed risk in the comparison group and the relative effect of the intervention. † Working Group grades of evidence as follows. High quality: Further research is very unlikely to change our confidence in the estimate of effect. Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate. Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate. Very low quality: We are very uncertain about the estimate.¹ Kremer 2006²⁴: Intention-to-treat analysis not performed. 9 patients in abatacept group and 5 in placebo group excluded from analysis. ² Weinblatt 2007²⁰: 15 people randomized were not treated and not included in analysis. ³ Kremer 2003²³: Risk of attrition bias; less than 80% completion rate in treatment group at 12 months. ⁴ Number needed to treat (NNT) = not available (NA) when result is not statistically significant. NNT for dichotomous outcomes calculated using Cates' NNT calculator²¹. NNT for continuous outcomes calculated using the Wells calculator (Cochrane Musculoskeletal Group editorial office). ⁵ Outcome based on Weinblatt 2007²⁰. ⁶ Outcome based on Kremer 2006²⁴. ⁷ Weinblatt 2006²⁶; risk of attrition bias: less than 80% completion rate in the treatment group at 12 months. ⁸ Radiographic data obtained for 90% of study participants. ⁹ Based on 2 longterm extension studies (LTE) of RCT. Participants on placebo in the RCT switched to abatacept treatment. ¹⁰ Longterm serious adverse events based on observational data. Two RCT had a LTE phase in which people in the placebo group during the RCT switched to abatacept for the LTE. RR: Risk ratio; RCT: randomized controlled trial.