Summary of findings table

$A batacept \ (2 \ and \ 10 \ mg/kg) \ + DMARDs/biologic \ versus \ placebo \ + \ DMARDs/biologic \ for \ rheumatoid \ arthritis$

Patient or Population: patients with rheumatoid arthritis

Settings: International; clinic/hospital

Intervention: Abatacept (2 and 10 mg/kg) + DMARDs/biologic

Comparison: Placebo +DMARDs/biologic

Outcomes ACR 50% improvement Follow-up: 12 months	Placebo +DMARDs/ biologic 168 per 1000	Abatacept (2 and 10 mg/kg) +DMARDs/ biologic 371 per 1000 (291 to 474)	Relative Effect (95% CI) RR 2.21 (1.73 to 2.82)	No. of Participants (Studies) 993 (3 studies)	Quality of Evidence (GRADE) Moderate	Comments (95% CI) Absolute difference= 21% (16% to 27%). NNT=5 (4 to 7) ⁴ Relative percent
Pain measured at end of study on a 100 mm visual analog scale. Scale from 0 (better) to 100 (worse). Follow-up: 12 months.	The mean pain in the control group was 49.24 mm	The mean pain in the intervention group was 10.71 lower (12.97 to 8.45)		1425 (1 study ⁵)	Moderate 2	change=121% (73% to 182%). Absolute difference= -11% (-13% to -8.5%). NNT=5 (4 to 6) ⁴ Relative percent change=-18% (-22% to -14%).
Improvement in physical function (HAQ: greater than 0.3 increase from baseline, 0-3 scale) Follow-up: 12 months	393 per 1000	637 per 1000 (531 to 766)	RR 1.62 (1.35 to 1.95)	638 (1 study ⁶)	Moderate 1	Absolute difference= 24% (16% to 32%). NNT=5 (4 to 7) ⁴ Relative percent change=62% (35% to 195%).

Achievement of low disease activity state (DAS 28 less than 3.2, scale 0-10) Follow-up: 12 months	98 per 1000	424 per 1000 (278 to 646)	RR 4.33 (2.84 to 6.59)	683 (1 study ⁶)	Moderate 1	Absolute difference= 33% (26% to 39%). NNT=4 (3 to 5) ⁴ Relative percent change=333% (184% to 559%).
Total serious adverse events Follow-up: 6 to 12 months	121 per 1000	127 per 1000 (105 to 155)	RR 1.05 (0.87 to 1.28)	3151 (6 studies)	Moderate 1,2,3,7	Absolute difference= 1% (-2% to 3%). NNT=n/a ⁴ Relative percent change=5% (-14% to 29%).
Long-term serious adverse events Follow-up: 2 years	See comment	See comment	Not estimable	950 (2 studies ⁹)	Low ⁸	Number of patients with SAE: Genovese 2005: 103/357; 23.4 SAE/100 patient-years; 70% completed the LTE. Kremer 2006: 149/593; 16.3 SAE/100 patient-years; 90.5% completed the LTE

CI: Confidence interval; **RR:** Risk ratio; **NNT**=number needed to treat; **SAE**=serious adverse event GRADE Working Group grades of evidence

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.

Footnotes

¹ Kremer 2006: Intention to treat analysis not performed. 9 patients in abatacept group and 5 in placebo group excluded from analysis.

² Weinblatt 2006: 15 people randomized were not treated and not included in analysis

³ Kremer 2003: Risk of attrition bias - less than 80% completion rate in treatment group at 12 months

⁴ NOTE: Number needed to treat (NNT)=n/a when result is not statistically significant. NNT for dichotomous outcomes calculated using Cates NNT calculator (http://www.nntonline.net/visualrx/). NNT for continuous outcomes calculated using Wells Calculator (CMSG editorial office).

Outcome based on Weinblatt 2006
 Outcome based on Kremer 2006

⁷ Weinblatt 2007: Risk of attrition bias - less than 80% completion rate in the treatment group at 12 months

⁸ Long-term serious adverse events based on observational data. Two RCTs had a long-term extension (LTE) phase in which people in the placebo group during the RCT switched to abatacept for the LTE.

⁹ Based on 2 long-term extension studies (LTE) of RCTs. Participants on placebo in the RCT switched to abatacept treatment for the LTE.