Title of Research
Correlation of the Multi-Biomarker Disease Activity (MBDA) Score with Composite Rheumatoid Arthritis Disease Activity Measures in the AMPLE Study

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Summary of Research
A novel multi-biomarker disease activity (MBDA) score has been proposed to measure disease activity in rheumatoid arthritis (RA). Conflicting results regarding the score's validity have been reported in the literature. The researchers are therefore conducting a systematic review and meta-analysis of the MBDA in RA to better understand whether this blood test is a valid measure of disease activity.

Fleishman et al[1] reported on the validity of the MBDA in the Abatacept versus Adalimumab Comparison in Biologic-Naive RA Subjects with Background Methotrexate (AMPLE) trial using cross-tabulations of MBDA scores by composite RA disease activity to measure disease activity states (remission, low disease activity, moderate disease activity, high disease activity). The researchers request the MBDA scores as well as the composite RA disease activity measure scores, so that they can calculate correlation coefficients, which would be combined with results from other published studies in a random-effects meta-analysis. These data will contribute to an understanding of the validity of the MBDA as well as potential effect modifiers of the validity of the MBDA (such as select treatments).

Study Design
The researchers are conducting a systematic review and meta-analysis of all published studies reporting on the correlation of MBDA scores with American College of Rheumatology-endorsed RA disease activity measures. They plan to request existing scores for the MBDA and RA disease activity measures (DAS28-CRP, DAS28-ESR, CDAI, SDAI, RAPID-3) from each study time point (baseline, month 3, year 1, and year 2).

They hypothesize that the MBDA score correlates with composite RA disease activity measures, and that changes in multi-biomarker disease activity score correlate with changes in composite RA disease activity measures.

The primary objective is to calculate correlations of the MBDA with composite RA disease activity measures to be used as part of a broader meta-analysis. The secondary objective is to calculate correlations between changes in the MBDA with changes in composite RA disease activity measures, also to be used as part of a broader meta-analysis.

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[1] https://onlinelibrary.wiley.com/doi/full/10.1002/art.39714

Dr. England (who is completing his 3rd year of Ph.D. studies in biostatistics and epidemiology and has authored several articles on multivariable analyses in RA outcomes research), will be conducting the statistical analyses

Study Population
AMPLE study participants, both arms (abatacept, adalimumab), and all available time points.

Funding Source of Research
Unfunded

Requested Study
List NCT Number and title
IM101-235 (NCT00929864): Abatacept Versus Adalimumab Head-to-Head

Statistical Analysis Plan
The researchers will calculate correlation coefficients (Pearson or Spearman depending on the distribution of the data) between the MBDA and composite RA disease activity measures (DAS28-CRP, DAS28- ESR, CDAI, SDAI, RAPID-3). 2. They will calculate correlation coefficients (Pearson or Spearman depending on distribution of the data) between change in the MBDA and change in composite RA disease activity measures (DAS28-CRP, DAS28-ESR, CDAI, SDAI, RAPID-3) from baseline to each of the three follow-up time points (month 3, year 1, year 2).

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