Reviewer’s report

Title: Malignancy risk in Australian rheumatoid arthritis patients treated with anti-tumour necrosis factor therapy: an update from the Australian Rheumatology Association Database (ARAD) prospective cohort study

Version: 0 Date: 28 Aug 2018

Reviewer: Gregory Gardner

Reviewer's report:

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This is a well written and discussed manuscript reviewing the malignancy risk of patients with RA with or without exposure to TNF agents. Methods are clear and statistics appear appropriate for data analysis. The limitation of the paper are also, in general, well discussed. The concept and results are not unique and generally do not add anything new to our understanding of TNFi risk in the area of malignancy with the exception of the observed increased risk of lung cancer that has not generally been seen in multiple other studies. I would like to see a bit more discussion on lung cancer and RA and some speculation on the authors part to explain their data. The results though do add to the overall reassurance that TNFI are safe.

The authors explain that participation in the database is voluntary. Is there any way to look at cancer risk among all RA patients in Australia given the required reporting to reassure the reader that this group is not somehow different that RA patients in general? If not easily done I would add this to the limitations discussion. Finally, the MOA of the fusion protein etanercept is a bit different than the monoclonal or monoclonal-like TNFis. Approximately 50% of patient on TNFis are on etanercept and the rest on the Mabs. They say there is not sufficient data to analyze individual TNFi but what about fusion protein vs Mabs?

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

Yes

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Yes
Are the conclusions drawn adequately supported by the data shown?
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Yes

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I am able to assess the statistics

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