Reviewer's report

Title: Effect of 12 months of testosterone replacement therapy on metabolic syndrome components in hypogonadal men: data from the Testim Registry in the US (TRiUS)

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Reviewer: Hugh H Jones

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This manuscript confirms the known association of low testosterone with metabolic syndrome. The authors report that in those men with metabolic syndrome TRT results in a reduction in waist circumference, BP and fasting blood glucose.

I have the following comments:-

1. In the background the authors state that there have been only 3 placebo-controlled trials (15-17). They have not included the Moscow study (Kalinchenko et al 2010 Clinical Endocrinology. This should be included.

2. As this is a prospective observational study it cannot be considered to be as powerful as a double-blind placebo controlled trial. The major problem is that there is no data supplied on concomitant medication. Clearly this is a confounding factor which may affect the results. Men with metabolic syndrome are more likely to be on medication for lipid lowering, blood pressure, anti-obesity drugs and diabetic medications. They are therefore more likely to have changes in these treatments optimising therapy and hence this will affect the secondary outcomes.

3. Table 4 shows significant differences after TRT by baseline testosterone level quartiles in TT but not FT this needs explanation.

4. In the discussion reference 31 is Yialmas et al which is not correct for sentence on prostate cancer. In Yialmas patients had IHH.

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.