Author’s response to reviews

Title: Randomized, controlled, parallel-group prospective study to investigate the clinical effectiveness of early insulin treatment in patients with latent autoimmune diabetes in adults.

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Dear Editor,

We have applied to the Multi-centred Ethics committee for the following amendment:

Step 3: Life style modification and Glitazone [Rosiglitazone]. Patients with a HbA1c of 7% or above will be given 4 mg once per day for 3 months. If after a 3 month period the HbA1c remains at 7% or above then titrate to maximal dose of 4 mg twice per day with or without Metformin. If HbA1c remains at 7% or above for an additional 3 months then move to step 4. Therefore, glitazone monotherapy will be used if Metformin intolerant otherwise glitazone will be added to the metformin (as per standard practice). Before initiation of Rosiglitazone a repeat medical history will be taken with special emphasis on cardiovascular disease, if patients have a history of cardiovascular disease (defined as IHD, PVD) they will not be initiated on Rosiglitazone but will move directly to Step 4 (insulin). Patients on rosiglitazone will be monitored using the adverse events form, for symptoms of heart disease specifically for chest pain and shortness of breath. Any adverse events suggestive of heart disease will result in Rosiglitazone being discontinued and the patient moving to step 4.

This amendment has been written by the data safety committee. The date for MREC review will be in the next two weeks.
On condition that the ethics committee approve this amendment we would like to submit the revised protocol which is attached.

With very good wishes and thanks

Dr Sinead Brophy
(on behalf of the LADA team)