Online supplement

Methods

Eligible subjects aged 30 to 85 years with an existing diagnosis of T2DM and DME with visual impairment were offered a screening sleep study via their Ophthalmology Centre. Domiciliary cardiopulmonary sleep study equipment (ApneaLink, ResMed) was posted to their homes. Automatic analysis of the studies was performed, with manual review.

Randomisation was performed with minimisation for: office blood pressure (above/below 140/90), OSA severity (above/below ODI 40 per hour), HbA1c (above/below 58 mmol/mol) and visual acuity severity (above/below ETDRS of 69 letters). If both eyes were eligible, one eye was randomly selected by computer.

Results

Of the 131 people randomised, 32 patients had two eligible eyes for the study; 20 had right eye randomised. All data from participants from one site were excluded (n=2, both control) as it became clear at the end of the trial that the site had not completed the trial protocol specifications. Another site failed to provide photographs for grading. Some photographs from other sites had not been completed to the protocol specifications and were ungradable.

Safety

There was no significant difference between the proportion of patients experiencing an adverse event or serious adverse event between treatment groups.