Reviewer's report

Title: A randomized controlled trial of the efficacy and safety of twice-daily saxagliptin plus metformin combination therapy in patients with type 2 diabetes uncontrolled on metformin monotherapy

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Reviewer: sten Madsbad

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In the present study the efficacy and safety of saxagliptin 2.5 mg BID versus placebo as add on to metformin in patients with type 2 diabetes was compared in a multicenter, randomized double-blind, parallel group trial. The primary efficacy variable was changes in HbA1c after 12 weeks. After 12 weeks the reduction in hba1c, fasting plasma glucose (p=0.12) was greater in the saxagliptin group compared with placebo treatment. More patients treated with saxagliptin reached HbA1c < 7.0 % and < 6.5 %. There was no safety concerns.

Several previous studies have evaluated saxagliptin 5 mg once daily as add on to metformin (ref 9-14). Therefore, the present study is not adding much new information about efficacy of saxagliptin. Furthermore, the duration of present study was only 12 weeks and rather few patients were randomised. The present study is provided in the support of a fixed combination pill of saxagliptin and metformin.

The design of the study is adequate and the data is well presented.

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.

Declaration of competing interests:

I declare that I have no competing interests´