

Novo Nordisk stripped comment

CSII for the treatment of diabetes (review)From:  
Sent: 20 September 2007 11:41  
To: Christopher Feinmann  
Subject: CSII for the treatment of diabetes (review)

Attachments: Raslova erratum.pdf; Raslova\_Diab\_Res\_Clin\_Pract\_66\_(2004)  
\_193\_201 - type 2.pdf

Dear Mr Feinmann

Thank you for the opportunity to review the assessment report for the continuous subcutaneous insulin infusion for the treatment of diabetes. Are comments are as follows:

a.. whilst it is correct that the fast-acting insulin analogues currently available are aspart, lispro and glulisine, none of the studies referred to in this report involve glulisine. We therefore feel that it is inappropriate to include this insulin in the review of CSII therapy with analogue insulin.

b.. The report states that there is no evidence that MDI with analogue insulins is superior to that with human insulins in type 2 patients, based on the findings of the Cochrane review by Siebenhofer et al. However, we would request that the Appraisal Committee also consider results of the study by Raslova et al<sup>2,3</sup> (references attached). This study showed that basal-bolus therapy with insulin detemir and insulin aspart in type 2 patients gave comparable glycaemic control to NPH and human soluble insulin, but with significantly less nocturnal hypoglycaemia, less weight gain and lower day-to-day variation in fasting plasma glucose. This study was not included in the Cochrane review as it's duration was 22 weeks, with Siebenhofer et al only considering studies of 24 weeks or longer.

Kind regards

1. Siebenhofer A, Plank J, Berghold A, Jeitler K, Horvath K, Narath M et al. Short acting insulin analogues versus regular human insulin in patients with diabetes mellitus. Cochrane Database of Systematic Reviews. Cochrane Database of Systematic Reviews 2006 Issue 2 Chichester (UK): John Wiley & Sons Ltd, 2006

2. Raslova K, Bogoev M, Raz I, Leth G, Gall M-A, Hancu N. Insulin detemir and insulin aspart: A promising basal-bolus regimen for type 2 diabetes. Diabetes Research and Clinical Practice 66, 2004, 193-201

3. Raslova K, Bogoev M, Raz I, Leth G, Gall M-A, Hancu N. Corrigendum to "Insulin detemir and insulin aspart: A promising basal-bolus regimen for type 2 diabetes". Diabetes Research and Clinical Practice 72, 2006, 112

<<Raslova erratum.pdf>> <<Raslova\_Diab\_Res\_Clin\_Pract\_66\_(2004)\_193\_201 - type 2.pdf>>

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