



May 3, 2021

Summary attachment for the trial:

- **EudraCT number: 2012-004883-23**
- **Title of trial: Individually tailored treatment in type 2 diabetes**
- **Sponsor name: Henning Beck-Nielsen**

Early termination

Due to recruitment issues the randomized trial was terminated early. The trial was redesigned and a new non-randomized trial was initiated.

After reassessment of the new protocol, the Danish Medicines Agency decided that the study was not assessed as being subject to notification according to Lægemiddeloven § 88, subsection 1. The study should therefore not be reported to Danish Medicines Agency, as notified in an e-mail from April 29 2016. The motivation for the decision was that the new trial tested two overall treatment strategies, without randomization, using only medication according to label.

The End of Trial Declaration for the study was sent to the Danish Medicines Agency on June 3 2016. Receipt was acknowledged by the Danish Medicines Agency on June 16 2016 via e-mail.

Summary

By end of the randomized trial, 56 patients had been enrolled, 33 patients in the control group with standard care and 23 patients with individualized care. No serious adverse events had been reported at the time of termination in either group. No follow-up visits with data acquisition had been undertaken at the time of early termination. No relevant results are therefore available for reporting.