

Treatment with insulin (long-acting basal insulin analogues, NPH insulin, or combination insulin; with or without OAD therapy since ≥ 3 months

Group 1

Insulin glargine (titrated acc. FBG) + Metformin (2 x 850mg daily)

Group 2

Insulin glargine (titrated acc. FBG) + Pioglitazone (2 x 15mg daily)

Group 3

Insulin glargine (titrated acc. FBG) + Metformin (2 x 850mg daily) + Pioglitazone (2 x 15mg daily)

Visit

V1

V1.1

V2

V3

V4

V5

V6

Time
(days)

-14
at least

-14
at least

0

42 $\pm$ 5

84 $\pm$ 5

126 $\pm$ 5

168 $\pm$ 5

Initial run-in phase of at least 2 weeks with insulin glargine (monotherapy) titrated to FBG ≤ 7.8 mmol/L

Treatment phase of 6 months
Titrated to FBG < 6.7 and ≥ 4.5 mmol/L