Figure 1

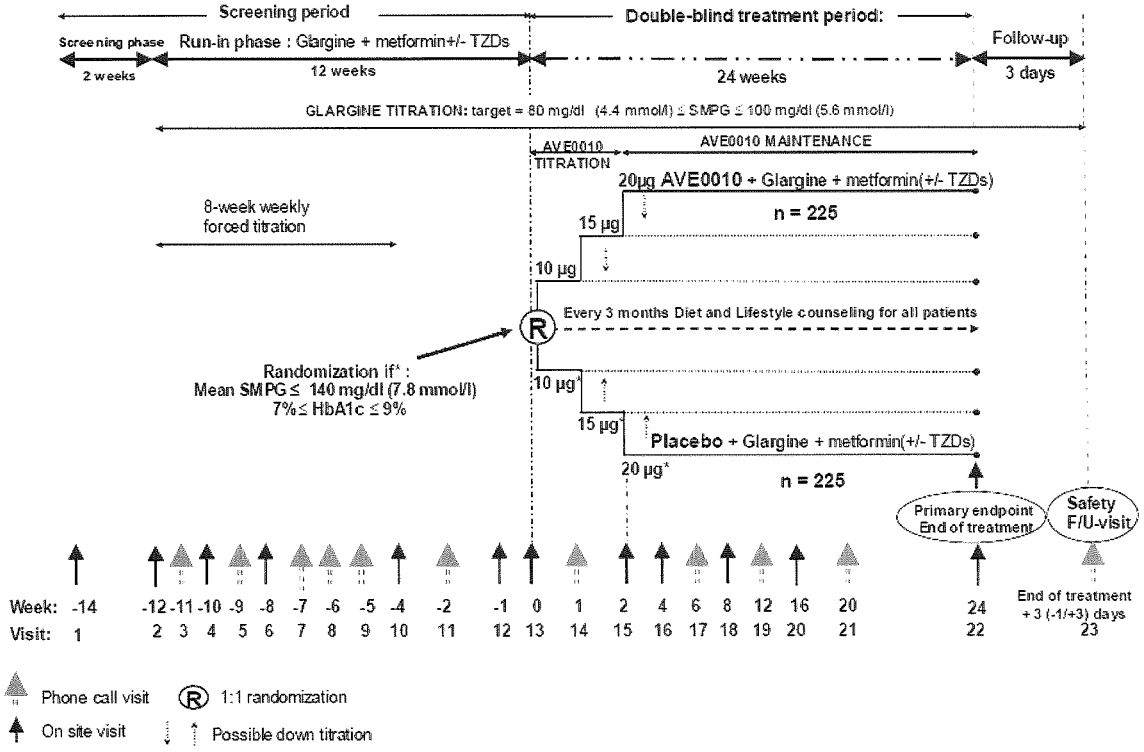
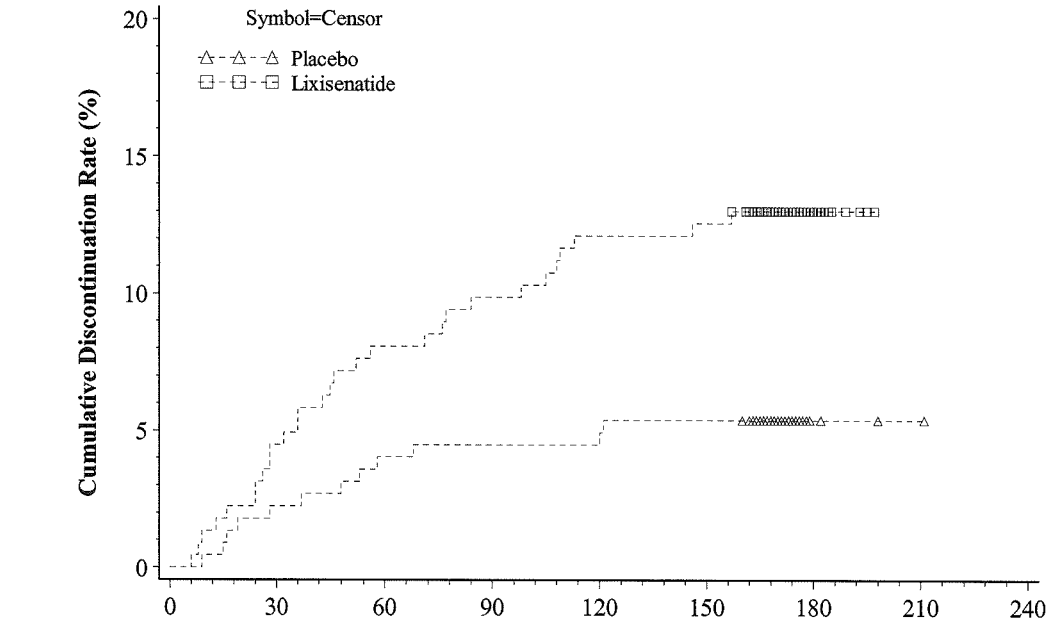

Screening period
Double-blind treatment period:
Screening phase
2 weeks
Run-in phase : Glargine + metformin+/- TZDs
12 weeks
24 weeks
Follow-up
3 days
GLARGINE TITRATION: target = 80 mg/dl (4.4 mmol/l) ≤ SMPG ≤ 100 mg/dl (5.6 mmol/l)
AVE0010 TITRATION
AVE0010 MAINTENANCE
20µg AVE0010 + Glargine + metformin(+/- TZDs)
n = 225
8-week weekly forced titration
15 µg
10 µg
Every 3 months Diet and Lifestyle counseling for all patients
R
Randomization if* :
Mean SMPG ≤ 140 mg/dl (7.8 mmol/l)
7% ≤ HbA1c ≤ 9%
10 µg*
15 µg
Placebo + Glargine + metformin(+/- TZDs)
20 µg*
n = 225
Primary endpoint End of treatment
Safety F/U-visit
Week: -14 -12 -11 -10 -9 -8 -7 -6 -5 -4 -2 -1 0 1 2 4 6 8 12 16 20 24
Visit: 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22
End of treatment +3 (-1/+3) days
23
Phone call visit
R 1:1 randomization
On site visit
Possible down titration

Figure 2



Number at Risk									
Placebo	223	218	214	213	213	211	4	1	0
Lixisenatide	223	213	205	201	196	195	12	0	0

Figure 3

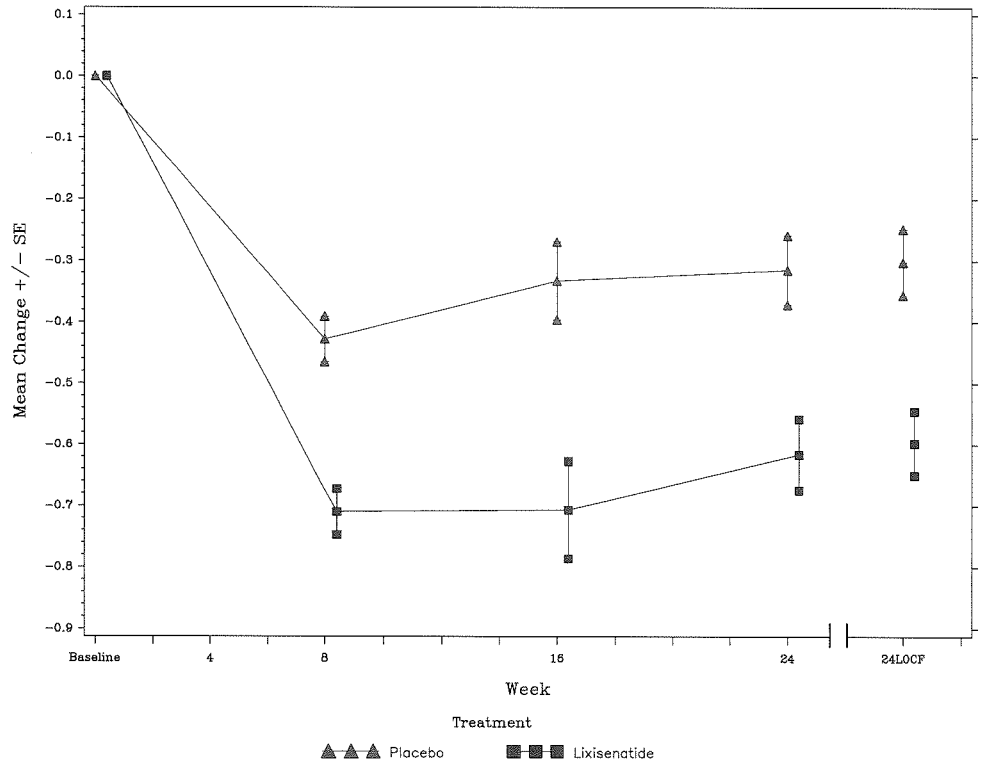


Figure 4

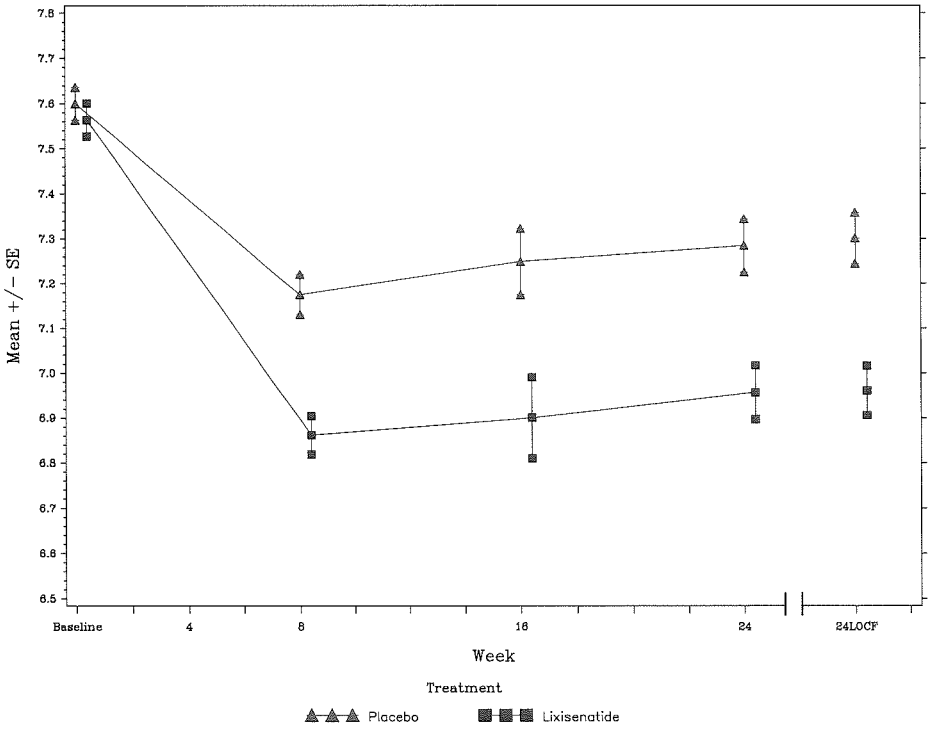


Figure 5

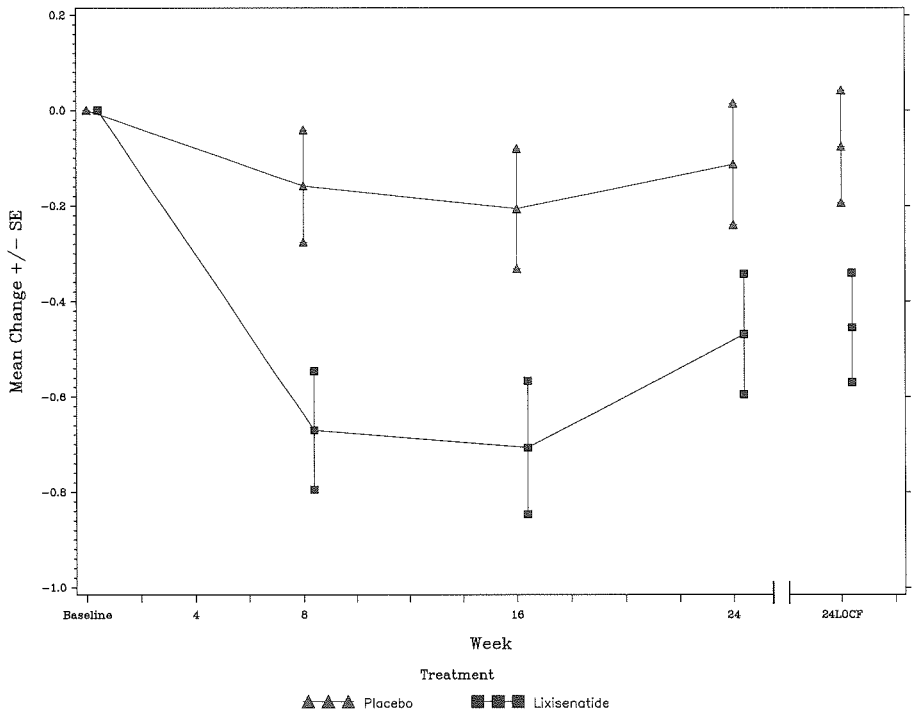


Figure 6

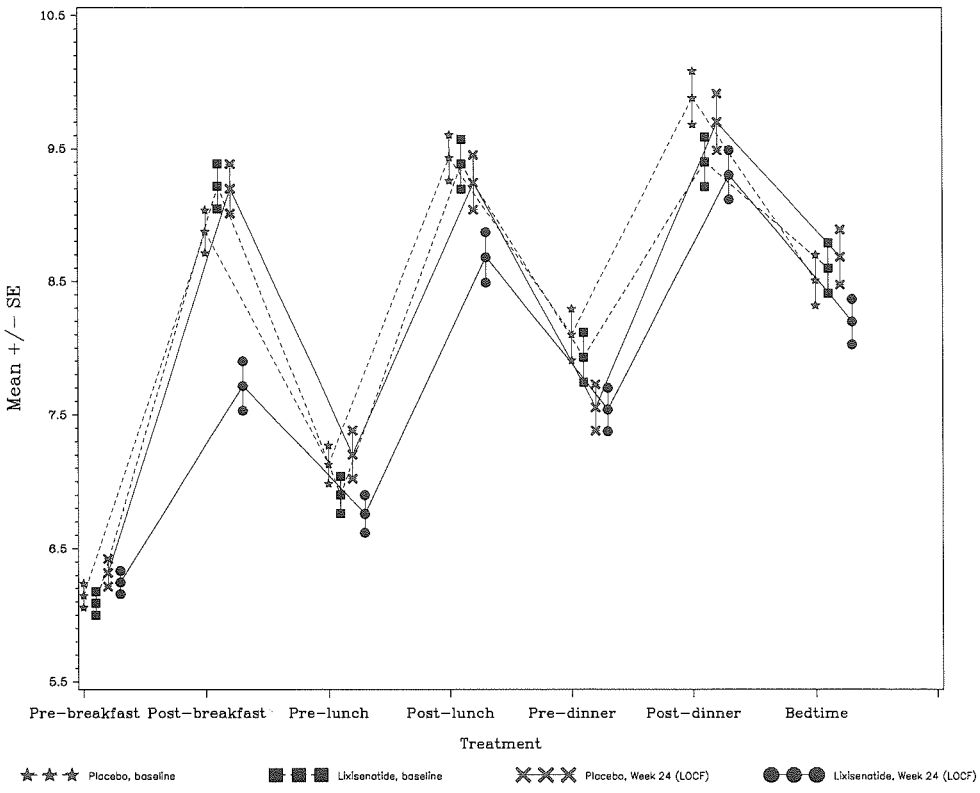


Figure 7

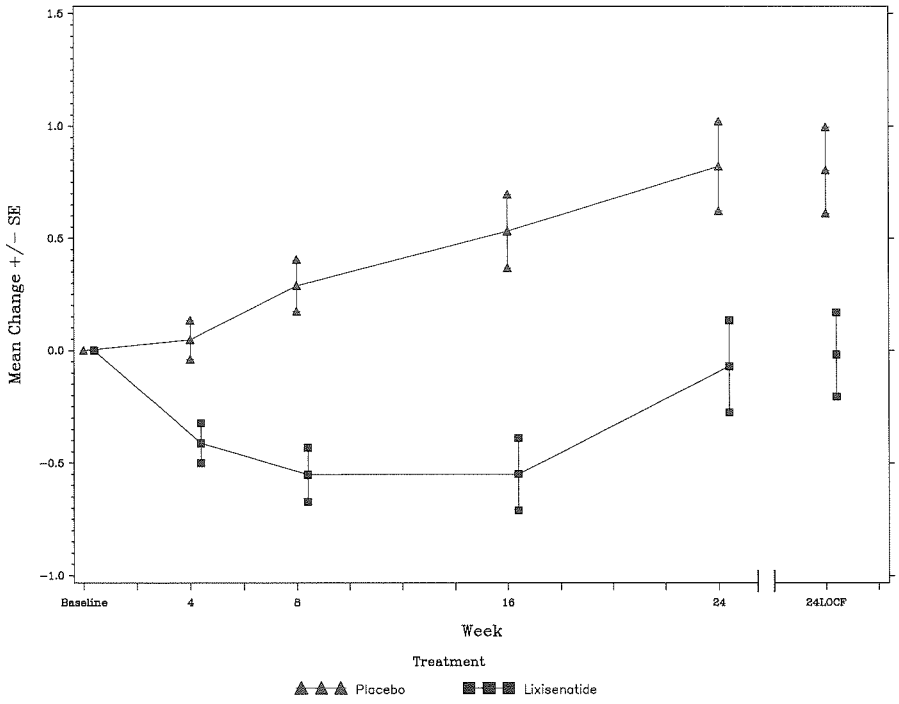


Figure 8

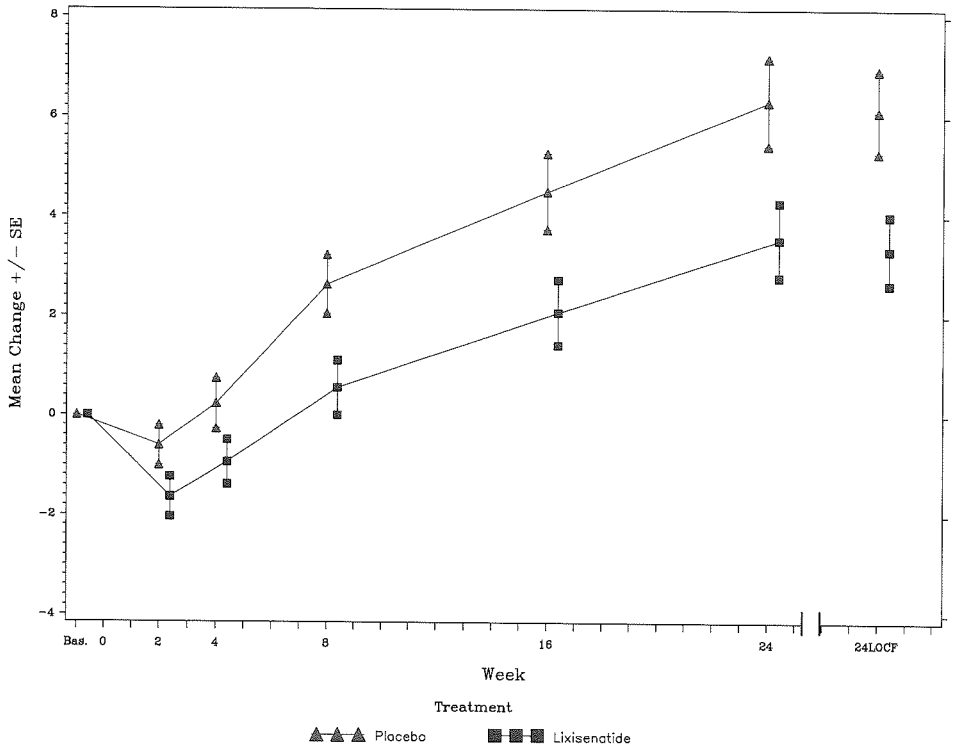


Figure 9

