

**Title:** Safety and Effectiveness of insulin Analogs in People with Type 2 Diabetes and End-Single Renal Disease in the Alchieve Study

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**Abstract:** Alchieve was a 24-week non-interventional study evaluating insulin analogs in 28 countries of 66,726 people with type 2 diabetes who has started insulin detemir, insulin aspart or biphasic insulin aspart 30 in 4 weeks prior to entry. This analysis investigated outcomes in people with/without end-stage renal diseases (ESRD) (n=647 and n=56,505, respectively) At baseline 11.3%,10.7% and 49.1% of those with ESRD, and 5.9%, 6.6% and 59.9% of those without ESRD were treated with aspart. basal insulin + aspart or biphasic insulin aspart 30, respectively in both groups, glycemic control improved after 24 weeks (HbA<sub>1c</sub> fasting plasma glucose and postprandial plasma glucose reduced significantly from baseline (p<0.001) in both groups) (Table). Overall hypoglycemia decreased from 8.02 to 1.62 events/person-year from baseline to week 24 in those with ESRD and from 3.25 to 1.77 in those without ESRD. Major hypoglycemia decreased from 1.87 to 0.000 events/person-year in those with ESRD and from 1.77 to 0.007 in those without ESRD. Triglycerides and systolic blood pressure decreased significantly (p<0.001) in both groups. there was no significant change in body weight. In the Alchieve study, insulin analog therapy was associated with improved glycemic control and reduced risk of hypoglycemia in people with type2 diabetes with and without ESRD after 24weeks of treatment.

Clinical Outcomes After 24 Weeks of Treatment with Insulin Analogs.		
	End-stage renal disease (n=647)	No end-stage renal disease (n=56,50.5)
HbA <sub>1c</sub> (%)	9.4(2.1)	9.5(1.8)
Baseline	-1.9(2.0)*	-2.1 (1.7)*
Change from baseline		
FPG (mg/dl)	184.5 (74.6)	195.0 (63.6)
Baseline	-55.5 (75.2)*	-67.8 (63.5)*
Change from baseline		
PPG (mg/dl)	252.7 (88.8)	268.6 (80.6)
Baseline	-78.9 (92.9)*	-95.5 (81.6)*
Change from baseline		
PPG (mmol/l)	14.0 (4.9)	14.9 (4.5)
Baseline	-4.4 (5.2)*	-5.3 (4.5)*
Change from baseline		
Overall hypoglycemia, events/ patient-year	8.02	3.25
Baseline	1.62	1.77
Week 24		
Major hypoglycemia, events/ patient-year	1.87	1.77
Baseline	0.000	0.007
Week 24		
Body weight (kg)	72.2 (15.6)	73.8 (15.1)
Baseline	0.2 (3.9)	0.0 (3.7)
Change from baseline		
Insulin dose, (U/kg/day)	0.58 (0.36)	0.55 (0.29)
Pre-study	0.47 (0.28)	0.44 (0.24)
Baseline	0.54 (0.32)	0.51 (0.27)
Week 24		
Creatinine (μmol/l)	113.2 (59.9)	80.2 (32.0)
Baseline	-12.9 (32.9)*	-3.7 (24.5)*
Change from baseline		
Triglycerides (mmol/l)	2.2 (1.1)	2.1 (1.1)
Baseline	-0.3 (0.8)*	-0.3 (0.9)*
Change from baseline		
SBP (mmHg)	142.7 (21.9)	134.1 (18.0)
Baseline	-6.5 (21.1)*	-6.2 (17.2)*

Change from baseline		
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