A randomised clinical trial investigating the effect of sitagliptin versus placebo in patients with Type 2 Diabetes Mellitus having a history of cardiovascular disease and a hemoglobin A1c (HbA1c) of 6.5% to 8.0%

1 Treatments

**Studied treatment**  
sitagliptin phosphate, one 50 mg or one 100 mg tablet (dose dependent on renal function) orally, once daily

**Control treatment**  
placebo

2 Patients

**Patients**  
patients with Type 2 Diabetes Mellitus having a history of cardiovascular disease and a hemoglobin A1c (HbA1c) of 6.5% to 8.0%

**Inclusion criteria**  
1) Patient has Type 2 Diabetes Mellitus; 2) Patient's HbA1c is between 6.5% (48 mmol/mol) and 8.0% (64 mmol/mol) on stable dose(s) of antihyperglycemic agent(s), including insulin; 3) Patient has preexisting cardiovascular disease;

**Exclusion criteria**  
1) Patient has a history of type 1 diabetes mellitus or ketoacidosis.; 2) Patient is not able to take sitagliptin;

3 Methods

**Blinding**  
double-blind

**Design**  
Parallel groups

**Centers**  
multicenter

**Geographical area**  
38 countries

**Sample size**  
14671 ( 7332 / 7339 )

**Hypothese**  
Non inferiority

**ArretTrt1**  
-

**ArretTrt0**  
-

**PeriodeInclusion**  
dec 2008 - jul 2012
4 Results

<table>
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<tr>
<th>Endpoint</th>
<th>T1</th>
<th>T0</th>
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<th>95% CI</th>
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5 References


6 Comments