

← [History of this study](#) ↑ [Current version of this study](#)

View of NCT01196546 on 2010_09_07

ClinicalTrials Identifier: NCT01196546

Updated: 2010_09_07

Descriptive Information

Brief title Efficacy and Safety of Combination Therapy of Vildagliptin/Metformin in Patients in Type 2 Diabetes Mellitus (T2DM)

Official title Multi-center, Open-label, 24-week Study to Demonstrate the Efficacy and Safety of Combination Therapy of Vildagliptin/Metformin 50/500 or 50/1000 mg Twice Daily in Patients With T2DM Inadequately Controlled With Metformin

Brief summary

This study will assess the efficacy and safety of combination therapy of vildagliptin/metformin in patients with T2DM inadequately controlled with metformin 1,000 mg/day.

Detailed description

Phase Phase 4

Study type Interventional

Study design Treatment

Study design Open Label

Study design Single Group Assignment

Primary outcome Measure: HbA1c reduction
Time Frame: 24 weeks after treatment
Safety Issue? No

Secondary outcome Measure: Proportion of patients who achieve target of HbA1c<6.5% at the end of study
Time Frame: 24 weeks after treatment
Safety Issue? No

Secondary outcome Measure: To evaluate the effect of combination therapy of vildagliptin (50 mg) plus metformin (500 or 1000 mg) twice daily on FPG and BMI, safety and tolerability profiles
Time Frame: 24 weeks after treatment
Safety Issue? Yes

Enrollment 200 (Anticipated)

Condition Type 2 Diabetes Mellitus

Arm/Group Arm Label: Vildagliptin/metformin Experimental

Intervention Drug: vildagliptin/metformin Arm Label: Vildagliptin/metformin

Recruitment Information

Status Recruiting
Start date 2010-03
Primary completion date 2011-06 (Anticipated)

Criteria

Inclusion Criteria:

- Type 2 Diabetes mellitus patients who are treated with metformin monotherapy 1,000 mg daily for at least 3 months
- The patient is required to have HbA1c 6.5-11.0%
- BMI in the range of 22-48 kg/m²

Exclusion Criteria:

- Severe or uncontrolled Type 2 diabetes mellitus (HbA1c > 11.0%)
- Acute metabolic diabetes complications such as ketoacidosis or hyperosmolar state (coma) within the past 6 months
- Congestive heart failure requiring pharmacologic treatment
- Any of following within past 6 months: (1) myocardial infarction; (2) unstable angina (3) coronary artery bypass surgery or percutaneous coronary intervention
- Liver disease such as cirrhosis or chronic active hepatitis

Gender Both
Minimum age 18 Years
Maximum age 78 Years
Healthy volunteers Yes

Administrative Data

Organization name Novartis
Organization study ID CLMF237ATH01
Sponsor Novartis
Health Authority Thailand: Ethical Committee