← 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