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← 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

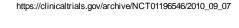
Safety Issue? Yes

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

GenderBothMinimum age18 YearsMaximum age78 YearsHealthy volunteersYes

Administrative Data

Organization name Novartis

Organization study ID CLMF237ATH01

Sponsor Novartis

Health Authority Thailand: Ethical Committee

