

PROTOCOL SUMMARY

Name of Sponsor Company: Takeda Pharma GmbH Collaborators: -	Drug Under Study: Pioglitazone 30mg, 45mg
Brief Title of Protocol: Pilot Trial studying the Effects of Pioglitazone in Comparison to Placebo on Myocardial Function and Oxidative Stress in Patients with Type II Diabetes and Insulin Resistance undergoing elective PTCA	
Protocol Number: D-Pio-111 (ATS K021)	Phase: II
Interventions: Study drug, placebo control Intervention Type: Drug Intervention Name: Pioglitazone 30 mg (week 1), 45 mg (week 2-3), vs. placebo	
Study Description: Treatment with Pioglitazone was shown to improve several vascular and myocardial parameters in patients with and without diabetes. In addition, Pioglitazone had shown to inhibit smooth muscle proliferation and neointima tissue proliferation after catheter intervention. The aim of this study is to compare the effects of pretreatment with Pioglitazone in comparison to Placebo in patients receiving PTCA on myocardial and endothelial Stress Primary endpoint: Incidence of Cardiac Troponin I elevation (> 1 ULN) at 24 h post Stent-PCI Sec. endpoint: To investigate the effect of Pioglitazone compared to Placebo on Incidence of CK-MB elevation at 24h post Stent-PCI Mean peak values of Troponin I and CK-MB 2h – 24h post Stent-PCI Time course until day 7 of: Troponin I hs-CRP Nitrotyrosin asymmetric Dimethylarginin (ADMA) E-Selectin Myoglobin Proinsulin intact Adiponectin Visfatin	
Study Type: Prospective, comparative, randomized and parallel two arm pilot study	
Study Status: recruiting	
Study Purpose: To evaluate the effects of Pioglitazone in comparison to Placebo on myocardial and endothelial stress in patients undergoing elective PTCA	

Condition or Disease: T2D, insulin resistance, patients with elective PTCA

Key Criteria for Inclusion:

- Stable coronary artery disease with planned Stent-PCI
- Type II-diabetics and/or IRIS II score ≥ 50

Key Criteria for Exclusion:

Stent-PCI within less than 15 days after the screening visit

Planned multivessel intervention

Use of systemic corticosteroids within the last 3 months prior to screening visit

Anamnestic history of hypersensitivity to the study drugs or to drugs with similar chemical structures

A history of significant cardiovascular (NYHA stage II - IV), respiratory, gastrointestinal, hepatic (ALAT > 2.5 times the normal reference range), renal (creatinine > 1.2 mg/dL in women and > 1.5 in men), neurological, psychiatric and/or haematological disease as judged by the Investigator.

Pre-treatment with PPAR γ agonists within the 3 months prior to screening

Pre-treatment with insulin for more than 7 days within the last 3 months

If statin therapy applicable: change of medication within the last 4 weeks

Myocardial infarction within 3 months prior to screening visit

Pat < 18 or > 75 years