Synopsis

(according to ICH Topic E3 Structur and Content of Clinical Study reports – Annex I)

Name of Sponsor: Technische Universität München	
Name of Finished Product: Actos	
Name of Active Ingredient: Pioglitazone	
Title of Study: Analysis of cerebral, renal, peripheral, and retinal hemodynamics in adults with type 2 diabetes before, during, and after administration of pioglitazone or placebo	
Investigators: LKP (AMG):. Dr. med. Holger Poppert	
Study centre(s): Neurologische Klinik und Poliklinik der TU München PD Dr. Holger Poppert Ismaninger Str. 22 81675 München	
Publication (reference): na	
Studied period (years) **first patient in:** na **last patient out:** na	**Phase:** IIIb
Objectives: Aim of the study is to investigate changes in: 1.) cerebral blood flow by comparing changes in calculated CVMR 2.) renal function quantified by the calculated GFR and RPF using IN and PAH creatinine values 3.) peripheral diabetic vasculopathy and/or retinopathy quantified through FBF 4.) retinal vascular reactivity using RVA Changes of interest are the following: Change 1:From baseline to end of treatment (day 28) Change 2:From baseline to end of study (day 42) Change 3:From two weeks after treatment begin to end of treatment (days 14 and 28) Change 4:From baseline to two weeks after treatment begin (day 14)	
Methodology: Randomised, double-blind, placebo-controlled, single-centre clinical trial	
Number of patients (planned and analyzed): - planned sample size: 60 - analyzed sample size: 0	
Diagnosis and main criteria for inclusion:	

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- Written informed consent
- Age 18 - 95 years
- Fasting blood sugar (FBS) > 200 mg/dl and / or HbA1c ≥ 6,5% or antidiabetic treatment
- Adequate bilateral temporal bone windows for sufficient TCD examination and symmetrical perfusion of the middle cerebral artery (MCA)
- Cerebrovascular disease

Test product, dose and mode of administration, batch number: Pioglitazone 30 mg (Actos)

Duration of treatment / treatment schedule:

28 days; 30 mg/d

Reference therapy, dose and mode of administration, batch number:
placebo

1. Reference substance: placebo
2. Reference substance: n.a.

Unblinding: by emergency envelopes

Criteria for evaluation:
Changes in the cerebral vasomotor reactivity (CVMR), in RVA (Retinal Vessel Analyzer), RPF (retinal plasma flow) and FBF (forearm blood flow) from baseline to end of treatment (day 28).

Statistical methods:

n.a.

Summery – Conclusions:

The clinical trial was premature terminated without inclusion of any patient.

Date of the report: 26.08.2013