

GUID/02/GIm-Dia/001

**Comparative study on the efficacy and tolerability of a new combination of Glibenclamide (2,5 mg) + Metformin (850 mg) vs a standard combination of Glibenclamide (2,5 mg) + Metformin (400 mg), vs monotherapy with Glibenclamide (5 mg) and vs monotherapy with Metformin (850 mg), in the treatment of type 2 diabetes mellitus.**

This study is currently recruiting patients

**Sponsor:** Laboratori Guidotti SpA

**Intervention:**

- -Glibenclamide (2,5 mg) + Metformin (850 mg)vs
- -Glibenclamide (2,5 mg) + Metformin (400 mg)vs
- -Glibenclamide (5 mg)vs
- -Metformin (850 mg)

**Condition:**

420 male and female type 2 diabetic patients divided into four treatment's groups; aged from 35 to 70 years, in monotherapy with sulfonylhureas or metformin. All the patients have a diagnosis of Diabetes less then 10 years, HbA1c more then 7.0 % and less or equal to 10% and BMI between 25 and 40.

**Study type & design:**

Phase III, perspective, randomized, double blind, parallel groups study controlled with other treatments.

**Main criteria for inclusion:**

- Male and female (non pregnant or treated with contraceptives drug);
- Aged between 35 and 70 years;
- Type 2 diabetic patients treated with sulfonylhureas or metformin;
- Minimal therapeutical drug's oral doses: glibenclamide 10 mg, or glicazide 160 mg, or glimepiride 4 mg, or metformin 1,5 g.
- Diagnosis of Diabetes less then 10 years;
- In non optimal metabolic control: HbA1c more then 7.0 % and less or equal to 10 %;
- Fasting blood glucose more then 120 mg/dl and less or equal to 280 mg/dl;
- BMI between 25 and 40). -With informed consens signed

**Main criteria for exclusion:**

- Type 1 diabetic patients;
- Patients affected by other serious illness;
- Patients with cardiovascular diseases less then 6 months before the -4 visit (MI, angina, heart failure, claudicatio intermittens );
- Patients with cerebrovascular diseases , AIT included, less then 6 months before the -4 visit;
- renal or hepatic serious diseases;
- neoplastic diseases;
- Women in the lactation time;
- Women not treated with contraceptives drug;
- No compliance to the study treatment.