

Guid/05/Met-GDM/001

Assessment of effects of a 12-month treatment with Metformin on insulin action and secretion in women with prior gestational diabetes mellitus (GDM)

This study is currently recruiting patients

Sponsor: Laboratori Guidotti Spa

Intervention: Metformin 850mg

Condition: Diabetes type 2

Study type & design:

double blind, multicentre, randomised, placebo-controlled, parallel group study design

Main criteria for inclusion:

Subjects meeting all the following criteria will be considered for enrolment into the study:

- 1) Female subjects aged ≥ 18 and ≤ 45 years;

- 2) Caucasian race;
- 3) History of prior GDM (in the screening) during pregnancy, defined according to Carpenter and Coustan (7) criteria, i.e. a FPG value ≥ 126 mg/dl or 2 or more of the following conditions after a 100-g oral glucose load in the oral glucose tolerance test (OGTT): 0' ≥ 95 mg/dl, 1h PG ≥ 180 mg/dl, 2h PG ≥ 155 mg/dl, 3h PG ≥ 140 mg/dl (2); or 2 or more of the following conditions after a 75-g OGTT: 0' ≥ 95 mg/dl, 1h PG ≥ 180 mg/dl, 2h PG ≥ 155 mg/dl ; or 1h PG ≥ 198 mg/dl after a screening test with (8) 50-g oral glucose load.
- 4) Altered Glucose Regulation (IFG or IGT) confirmed at the first post-partum follow-up after a 75-g oral glucose load in the OGTT, performed at entry in the time-window of 10 to 48 months after delivery, defined as a FPG value ≥ 100 mg/dl and < 126 mg/dl (IFG) according with latest classification (9) and/or or a PG value ≥ 140 mg/dl and < 200 mg/dl 2 hours after the glucose load.
- 5) Female of childbearing potential must use effective contraceptive measures for at least 1 month prior to the entry into the study and should continue to use the same contraceptive method during the overall study period. A pregnancy test at study entry is to be performed in childbearing potential women.
- 6) Written informed consent obtained.

Main criteria for exclusion:

Subjects presenting with any of the following will not be included in the study:

- 1) Patients diagnosed with type 1 insulin dependent diabetes mellitus (i.e. positivity for anti-GAD and for anti-IA2); in the event that results are not available at the end of run-in, patients with positivity to antibodies will be withdrawn from the study within the first post-baseline visit. In the case of availability of results obtained in the previous 48 months, they will be considered as valid confirmatory results and the test is not to be repeated at visit 1;
- 2) Diagnosis of diabetes in the 75-g OGTT performed at entry, defined as a FPG value ≥ 126 mg/dl and/or or a PG value ≥ 200 mg/dl 2 hours after the glucose load;
- 3) BMI ≥ 40 Kg/m²;
- 4) Impaired renal function as shown by serum creatinine ≥ 135 μ mol/l in males and ≥ 110 μ mol/l in females;
- 5) Impaired liver function as shown by transaminase levels \geq twice above the upper normal range;
- 6) History of hypersensitivity to metformin;
- 7) Pregnant or breast-feeding women, or women planning to become pregnant during the study;
- 8) Failure to use adequate contraception (women of current reproductive potential only);
- 9) Mental condition rendering the subject unable to understand the nature, scope, and possible consequences of the study;
- 10) Any clinically significant major organ system disease such as relevant cardiovascular, gastrointestinal, hepatic, neurological, endocrine, haematological or other major systemic diseases or infective diseases

making implementation of the protocol or interpretation of the study results difficult;

- 11) Patients with underlying concomitant medications requiring a long-term use of drugs potentially acting on glucose metabolism (e.g. corticosteroids, diuretics, beta-adrenergic drugs or others);
- 12) Treatment or likelihood of requiring treatment during the study period with drugs not permitted by the clinical study protocol;
- 13) History of drug or alcohol abuse within the last 2 years or current addiction to substances of abuse;
- 14) Any disease or condition that in the opinion of the investigator may interfere with the completion of the study;
- 15) Subject unlikely to comply with protocol, e.g., uncooperative attitude, inability to return for follow-up visits, and unlikelihood of understanding or completing the study procedures;
- 16) Receipt of an experimental drug or device within 12 weeks prior to study entry;
- 17) Previous enrolment in the present study.