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ObsErvationAl Study to analYse titration of the new Diamicron MR 60 mg formulation in daily clinical practice in a large population with uncontrolled type 2 diabetes

Submission date
07/02/2013

Recruitment status
No longer recruiting

Registration date
25/02/2013

Overall study status
Completed

Last Edited
16/04/2018

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Gliclazide is a well-known drug prescribed to control glucose levels in patients with type 2 diabetes mellitus. Diamicron MR 60 mg is a new modified-release formulation of gliclazide that enables the number of tablets per intake to be halved and allows gradual increase of dosage up to an optimal level. This new formulation is also expected to enhance compliance, meaning that more patients take their treatment properly and have better control of their diabetes.
The aim of the ongoing EasyDia program is to analyse how the new formulation Diamicron MR 60 mg is prescribed in daily clinical practice, notably of how rapidly and easily patients reach the optimal dosage.

Who can participate?
EasyDia is including over 5000 male or female patients aged 35 years or older with type 2 diabetes with glucose levels that are poorly controlled with diet or lifestyle measures or with other antidiabetic treatments (except insulin).

What does the study involve?
This is an observational study, which means that included patients are managed in exactly the same way as they would be if they were not participating in the program.

What are the possible benefits and risks of participating?
There should be no net benefit or risk for the participants as this is an observational study in which the participants will be treated as in normal practice. It should be noted that gliclazide has been in clinical use in other formulations since 40 years, and is not associated with any untoward safety issues.

Where is the study run from?
The study in taking place in 8 countries (Armenia, Russia, Switzerland, Malaysia, Georgia, The Lebanon, Slovenia, and Bangladesh) and all investigators are physicians in general practice or hospitals.

When is the study starting and how long is it expected to run for?
The first patient visit was in July 2011 and the study is expected to end in October 2013.

Who is funding the study?
The study is being funded by the French pharmaceutical company Servier.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
DME-5702-149

Study information

Scientific Title
ObsErvationAl Study to analYse titration of Diamicron MR 60 mg in daily clinical practice in a large population with uncontrolled type 2 diabetes

Acronym
EASYDia

Study objectives
A new formulation of modified-release gliclazide 60 mg (Diamicron MR 60 mg) has been developed with the aim of allowing gradual uptitration to optimal dosage as well as halving the number of tablets per administration at maintenance dosage. This 6-month, multicenter, open-label, non-randomized, non-comparative, observational study was designed to assess the

prescription of gliclazide MR 60 mg in primary care, notably during the titration phase of treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Slovenian National Medical Ethics Committee, 19/10/2011
All other centres will seek ethics approval before recruiting participants

Primary study design
Observational

Study design
Multicenter open-label observational study

Study type(s)
Other

Health condition(s) or problem(s) studied
Type 2 diabetes mellitus

Interventions
This observational study is performed in patients receiving gliclazide MR 60 mg as the basis of their treatment strategy:
1. Newly diagnosed patients will be initiated on gliclazide MR 60 mg.
2. Previously diagnosed patients will be switched to gliclazide MR 60 mg or receive it added on to their current treatment.

The starting dose of gliclazide MR 60 mg will be defined according to the judgment of the investigators and the Summary of Product Characteristics.

Dose increases will be made at each study visit (1, 2, and 3 months) according to fasting plasma glucose and patient characteristics (especially regarding elderly patients or those with renal insufficiency), up to a maximal dose of 120 mg (2 tablets) per day in a single intake at breakfast, before adding any other oral antidiabetic drug.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Diamicron MR 60 mg (gliclazide 60 mg)

Primary outcome(s)
Time to reach the efficient dose that provides optimal glycemic control, according to the investigator's judgment

Key secondary outcome(s)

1. Average daily dose of gliclazide MR 60 mg at the end of the study
2. Compliance assessed by a qualitative questionnaire (addressed to the investigators)
3. Treatment doses: repartition of each dose level in the population over time
4. Efficacy parameters (HbA1c and fasting plasma glucose): change versus baseline; percentage of patients achieving an HbA1c level 6.5% or lower, and 7% or lower
5. Safety parameters
6. Treatment acceptability with assessment of body weight change

Completion date
31/10/2013

Eligibility

Key inclusion criteria
Male or female patients with type 2 diabetes, aged 35 years or older, not optimally controlled (HbA1c 7.5% or higher, according to patient profile), including:
1. Newly diagnosed patients, in whom lifestyle recommendations have failed
2. Previously diagnosed patients, who are intolerant or have contraindication to current treatment, or in whom previous treatment has failed.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Requirement for insulin therapy
2. Severe liver or renal failure
3. Contraindication to gliclazide
4. Pregnancy or breast feeding
5. Treatment with miconazole

Date of first enrolment
01/07/2011

Date of final enrolment
31/10/2013

Locations

Countries of recruitment
Armenia

Bangladesh

Canada

Georgia

Lebanon

Malaysia

Russian Federation

Slovenia

Switzerland

Study participating centre
St Michael's Hospital
Toronto
Canada
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Sponsor information

Organisation
Institut de Recherches Internationales Servier (France)

ROR
https://ror.org/034e7c066

Funder(s)

Funder type
Industry

Funder Name
Institut de Recherches Internationales Servier (France)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	10/04/2018		Yes	No