Effectiveness of Novomix insulin versus NPH insulin with type 1 and 2 diabetic patients in Iran.

Protocol summary

Summary
Our aim is study the effectiveness of Insulin Novomix® in comparison with insulin NPH in patients with type 1 and 2 diabetes in Iran. The Inclusion criteria would be Male or female patients with type 1 and 2 diabetes; diabetic patients who are inadequately controlled blood glucose on their previous therapy that have HbA1c< 10%; diabetic patients who are administrated with Novomix or NPH. And the Exclusion criteria would be Patients occurrence of sever side–effects; suffering from diabetes in pregnancy; any refuse to participate in study. 60 diabetic patients would enrolled to study under Novomix or NPH regimen for 6 month. HbA1c is the outcomes.

General information

Acronym
IRCT registration information
IRCT registration number: IRCT201112038282N1
Registration date: 2012-02-16, 1390/11/27
Registration timing: registered_while_recruiting

Expected recruitment start date
2011-12-22, 1390/10/01
Expected recruitment end date
2012-02-20, 1390/12/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effectiveness of Novomix insulin versus NPH insulin with type 1 and 2 diabetic patients in Iran.

Public title
Effectiveness of Novomix insulin versus NPH insulin in diabetic patients in Iran.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Male or female patients with type 1 and 2 diabetes; diabetic patients who are inadequately controlled blood glucose on their previous therapy that have HbA1c< 10%; diabetic patients who are administrated with Novomix or NPH. Exclusion criteria: Patients occurrence of severe side–effects; suffering from diabetes in pregnancy; any refuse to participate in study.

Age
From 18 years old to 70 years old

Gender
Both

Phase
N/A

Groups that have been masked
None

Sample size
Target sample size: 60

Randomization (investigator's opinion)
Randomized

Blinding (investigator's opinion)
Not blinded

Placebo
Not used

Assignment
Parallel

Other design features

Secondary IDs
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tehran University of medical Sciences
Street address
Ghods ave., Enghalab bul., Tehran, Iran
City
Tehran
Postal code
Approval date
2012-01-04, 1390/10/14
Ethics committee reference number
90-03-33-15600-42485

Health conditions studied

1

Description of health condition studied
Diabetes mellitus
ICD-10 code
E10, E11
ICD-10 code description
Insulin-dependent diabetes mellitus and Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description
HbA1c
Timepoint
every 3 months
Method of measurement
laboratory tests

Secondary outcomes

1

Description
Costs of treatments
Timepoint
At the end of the study
Method of measurement
Economic evaluations

Intervention groups

1

Description
60 patients with type 1 and 2 diabetes will enrolled in this prospective randomized clinical trial study, these patients are divided randomly in two 30 person groups. In case group, Novomix® insulin would be prescribed. Daily dose of insulin will increase until to reach appropriate FBG level in weekly prescription. Treatment is recorded at the follow-up visit (at 6 month). Several factors will recorded monthly as clinical information during this study such as: BMI, HDL, LDL, VLDL, blood pressure, HbA1c, hypoglycemic episodes, FBG in other to studying costs of two types of prescription we measure direct and indirect costs and calculate Incremental Cost Effectiveness Ratio (ICER) based on decrease unit of BMI and HbA1c and FBG in US dollar.
Category
Treatment - Drugs

2

Description
60 patients with type 1 and 2 diabetes will enrolled in this prospective randomized clinical trial study, these patients are divided randomly in two 30 person groups. In control group, NPH insulin would be prescribed. Daily dose of insulin will increase until to reach appropriate FBG level in weekly prescription. Treatment is recorded at the follow-up visit (at 6 month). Several factors will recorded monthly as clinical information during this study such as: BMI, HDL, LDL, VLDL, blood pressure, HbA1c, hypoglycemic episodes, FBG in other to studying costs of two types of prescription we measure direct and indirect costs and calculate Incremental Cost Effectiveness Ratio (ICER) based on decrease unit of BMI and HbA1c and FBG in US dollar.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Endocrinology center, Imam Khomeyni hospital
Full name of responsible person
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Vice-chancellor for research
Street address
Tehran University of Medical Sciences
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
empty
Type of organization providing the funding
empty

Person responsible for general inquiries
Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Amir Farshchi
Position
Pharm D
Other areas of specialty/work
Pharmacoeconomics department, School of pharmacy, 16 Azar Ave.
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Web page address

Person responsible for scientific inquiries
Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Amir Farshchi
Position
Pharm D
Other areas of specialty/work
Pharmacoeconomics department, School of pharmacy, 16 Azar Ave.
City
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Fax
Email
farshchi.pharm@gmail.com
Web page address

Sharing plan
Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty