Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

In healthy human volunteers; study of Insulin Glargine (Basagine™) after single subcutaneous injection of 0.2 unit/Kg dose; compared with nothing and primarily to establish the PK parameters Cmax, Tmax and AUC in Pakistani population.

Protocol summary

Summary

Study Title: Pharmacokinetic evaluation of Insulin-Glargine (rDNA origin) 100 u/ml (Basagine™) in local healthy human volunteers after administration of a 0.2 units/Kg subcutaneous dose. Study Design: Open label, single period, single treatment, and single dose study in fourteen healthy volunteers. Goal/Objective: To determine AUC0–t, Cmax and, Tmax of the drug in Pakistani population Inclusion Criteria: Healthy male/female, Age: 18 to 50 years, BMI: 18-26 Kg/m2, Fasting plasma glucose: <6.0 mmol/l, non-smoker, non-alcoholic and no drug abuse. Exclusion criteria: Volunteers with any neuropathy, diabetes mellitus, Hypertension and any Cardio Vascular disease, positive test results for HBsAg, anti HCV and HIV antibody. Findings of hematology, biochemistry and ECG are out of range revealing clinical significance. Treatments: Single subcutaneous dose of Insulin-Glargine (rDNA origin; Basagine™) 0.2 units/Kg. Afterwards 5ml blood would be collected at 30 min, 15 min and 0 min before and 1, 2, 3, 4, 6, 8, 12, 16, 20, 22, 23, 24, 25 hours after drug administration. 120-240 ml 20% glucose will be given orally every 30 minutes to keep the blood glucose levels above 100mg/dl. Safety: Through physical examination, vital sign, adverse events, glucose monitoring and lab test monitoring on screening and at follow up after 72 hours. Throughout the study blood glucose levels would be monitored to maintain the blood glucose level between 3.3 to 7.7 mmol/liter. Measurements/ Analysis: Insulin and C-peptide through Chemiluminescence. Pharmacokinetic parameters would be determined by model independent method using PPstat soft ware. Ethical consideration: Approved from IRB and full compliance to ICH-GCP.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201203227978N2**
Registration date: **2012-04-01, 1391/01/13**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2012-04-01, 1391/01/13

Registrant information

Name
Tasneem Ahmad
Name of organization / entity
Pharma Professional Services, Karachi, Pakistan
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Pakistan
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(92-21) 34972358, 34820573
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Recruitment status

Recruitment complete

Funding source

Getz Pharma (Pvt) Ltd; Karachi, Pakistan

Expected recruitment start date

2012-06-22, 1391/04/02

Expected recruitment end date

2012-06-22, 1391/04/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
In healthy human volunteers; study of Insulin Glargine (Basagine™) after single subcutaneous injection of 0.2 unit/Kg dose; compared with nothing and primarily to establish the PK parameters Cmax, Tmax and AUC in Pakistani population.

Public title
A STUDY OF BASAGINE™ IN LOCAL HEALTHY HUMAN SUBJECTS TO EVALUATE ITS PHARMACOKINETIC BEHAVIOUR

Purpose
Other

Inclusion/Exclusion criteria
INCLUSION: Healthy male/female, Age:18 to 50 years, BMI: 18-26 Kg/m2, Fasting plasma glucose: <6.0 mmol/l (<108 mg/dl) or normal range and Non-smoker, non-alcoholic EXCLUSION: • Volunteers with any neuropathy, diabetes mellitus. • Any active allergic disease or a history of significant allergic disease. • Presence of renal, hepatic or gastrointestinal disease known to interfere with the drug absorption, distribution, metabolism or elimination with in last year. • Subject demonstrates protocol non-compliance (e.g. uncooperative attitude, & inability to finish study). • Participation in another study within last 2 months of 1st drug administration. • If donated blood within last 2 months preceding the study. • Age below 18 years and above 50yr. • Smoking within last 3 months prior to the drug administration and 6 hours after drug administration. • Ingestion of OTC drug (except Paracetamol) within last 14 days of 1st drug administration. • Participants with insufficient organ and/or bone marrow dysfunction. • Ingestion of investigational drug within 1 year prior to 1st drug administration. • Participants with an uncontrolled medical condition (i.e., hypertension, cardiac arrhythmias, CHF) that places the patient at risk by participating in the study. • Results of CBC, LFT, serum creatinine, fasting plasma glucose indicating significantly out of range and abnormal ECG. • Participants with any physical/mental disability • Subjects with known HIV, hepatitis B or hepatitis C infection, or autoimmune diseases. • History of major organ transplantation, new onset diabetes, unstable thyroid function. • Alcohol or drug abuse within the past year. • Known hypersensitivity to investigational drug • Positive drug of abuse test and alcohol test. • Intake of gutka, pan and any other thing containing nicotine 48 hours before and during study.

Age
From **18 years** old to **50 years** old

Gender
Male

Phase
4

Groups that have been masked
No information

Sample size
Target sample size: **14**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features
Open label, single period, single treatment, and single dose study in fourteen healthy volunteers.

Secondary Ids

1

Registry name
The Universal Trial Number (UTN)

Secondary trial Id
U1111-1129-4410

Registration date
2012-03-24, 1391/01/05

Ethics committees

1

Ethics committee

Name of ethics committee
Institutuional Review Board, Civil Hospital, Dow University of Health Sciences, Karachi

Street address
Institutuional Review Board, Civil Hospital, Dow University of Health Sciences, Karachi

City
Karachi

Postal code
74200

Approval date
2012-03-10, 1390/12/20

Ethics committee reference number
IRB-311/DUHS-12

Health conditions studied

1

Description of health condition studied
Diabetes mellitus

ICD-10 code
E10-E14

ICD-10 code description
Diabetes mellitus Without complications

Primary outcomes

1

Description

Serum levels of Inslin and C-peptide

Timepoint

30 min, 15 min before and 0, 1, 2, 3, 4, 6, 8, 12, 16, 20, 22, 23, 24, 25 hours after

Method of measurement

Serum concentrations of Insulin and C-peptide would be measured through Chemiluminescence.

Secondary outcomes

1

Description

Pharmacokinetic parameters: Cmax, Tmax and AUC0-t

Timepoint

Pharmacokinetic (PK) parameter will be determined: Area under the curve to the last measurable concentration (AUC_ 0-t) will be calculated by the linear trapezoidal rule. C_max and t_max would also be recorded form the drug concentration vs time profile.

Method of measurement

Pharmacokinetic (PK) parameter will be determined on the basis of measurement of exogenous and endogenous concentration of insulin; performed by means of model independent method using PPstat computer programs.

Intervention groups

1

Description

Administration of Insulin-Glargine (rDNA origin; 100 u/ml; Basagine™) 0.2 units/Kg subcutaneous dose

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dow University of Health Sciences (DUHS), Karachi

Full name of responsible person

Dr. Khaqan Ahmad

Street address

Dow University of Health Sciences (DUHS) Ojha Campus

City

Karachi

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Getz Pharma (Pvt) Limited

Full name of responsible person

Dr. Khawar Mehdi

Street address

Director Medical Affairs, 29-30, Secotr-27, Korangi Industrial Area

City

Karachi

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Getz Pharma (Pvt) Limited

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

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Pharma Professional Services, Karachi, Pakistan

Full name of responsible person

Ms. Ghousia Saba

Position

Chief Scientific Officer

Other areas of specialty/work

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Full name of responsible person

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Other areas of specialty/work

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Person responsible for updating data

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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