

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 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 AUC<sub>0-t</sub>, C<sub>max</sub> and, T<sub>max</sub> of the drug in Pakistani population Inclusion Criteria: Healthy male/female, Age: 18 to 50 years, BMI: 18-26 Kg/m<sup>2</sup>, 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

##### Country

Pakistan

##### Phone

(92-21) 34972358, 34820573

##### Email address

tasneem.ahmed@iccs.edu

#### 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/m<sup>2</sup>, 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**

Instituional Review Board, Civil Hospital, Dow University of Health Sciences, Karachi

**Street address**

Instituional 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 Insulin 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: C<sub>max</sub>, T<sub>max</sub> and AUC<sub>0-t</sub>

**Timepoint**

Pharmacokinetic (PK) parameter will be determined: Area under the curve to the last measurable concentration (AUC<sub>0-t</sub>) will be calculated by the linear trapezoidal rule. C<sub>max</sub> and t<sub>max</sub> would also be recorded from 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; Basagline™) 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****Street address**

8 Gulshan View, Gulshan-e-Iqbal, Karachi,

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**Province**

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Pharma Professional Services, Karachi, Pakistan

**Full name of responsible person**

Prof. Dr. Tasneem Ahmad

**Position**

CEO/ B.Pharm, M.Pharm, Ph.D.

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**Person responsible for updating data****Contact****Name of organization / entity**

Pharma Professional Services, Karachi, Pakistan

**Full name of responsible person**

Prof. Dr. Tasneem Ahmad

**Position**

CEO/ B.Pharm, M.Pharm, Ph.D.

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**City**

Karachi

**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*