Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

In local healthy human volunteers after single subcutaneous dose of 20 kDa peginteferon □-2a (from Unipeg□) evaluation of safety and pharmacokinetics of the drug

Protocol summary

Summary

Study Title: Pharmacokinetic and Safety evaluation of pegylated interferon α-2a from its commercial product "Unipeg□" in healthy human subjects. Study goal: To establish the Pharmacokinetic and safety of 20 kDa peginterferon (Unipeg) in Pakistani population. Study Design: Open label, single period, single treatment, and single dose study in healthy volunteers. Sample size: Ten Inclusion Criteria: Healthy male subjects, Age: 18-45 years, BMI: 18-26 kg/m2, Able to understand and give free written informed consent, Non-smoker, non-alcoholic Exclusion criteria: any illness, blood donation in last two months, OTC and any prescription drug in last 14 and 30 days respectively. Participation in another study within last 2 months Treatments: After 10 hour fasting; single dose of PEG-interferon alfa-2a 180mcg administered subcutaneously in the morning in abdominal region. 5ml blood was collected at 0, 1, 2, 3, 6, 12, 24, 36, 60, 84, 108, 132, & 156 hours after drug administration. Safety: through physical examination, vital sign, adverse events and lab test monitoring on screening, fifth day and at follow up after two weeks. CBC and ALT test for safety on day five and sixteen. Analysis: through ELISA Pharmacokinetics analysis: PK Parameters; AUC0–t, AUC0–∞, Cmax, Tmax and T1/2. determined by model independent method using PK-solution and PP-stat software Ethical consideration: Approved from independent ethics committee of ICCBS, University of Karachi, and full compliance to Declaration of Helsinki and ICH-GCP.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201111027978N1**

Registration date: **2012-02-11, 1390/11/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-02-11, 1390/11/22

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

2010-07-21, 1389/04/30

Expected recruitment end date

2010-08-05, 1389/05/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

In local healthy human volunteers after single subcutaneous dose of 20 kDa peginteferon □-2a (from Unipeg□) evaluation of safety and pharmacokinetics of

the drug

Public title
A STUDY OF UNIPEG® IN HEALTHY HUMAN SUBJECTS TO EVALUATE ITS SAFETY AND PHARMACOKINETIC BEHAVIOUR

Purpose
Other

Inclusion/Exclusion criteria
INCLUSION: Healthy human volunteers, BMI: 18-26 Kg/m2, non-smoker, non-alcoholic, with normal lab reports for CBC, LFT, HBsAg, Anti HCV, HIV antibody EXCLUSION: • 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 45yr. • 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 low blood counts and hematology results outside the normal range. (ANC) absolute neutrophile count should be > 1500/mm3 and platelete count should be grater then 50,000/ mm3 . • Participants with an uncontrolled medical condition (i.e., hypertension, cardiac arrhythmias, CHF) that places the patient at risk by participating in the study. • 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. • Concurrent therapy with immunosuppressive drugs or cytotoxic agents. • Alcohol or drug abuse within the past year. • Known hypersensitivity to investigational drug • Participants with uncontrolled brain metastases or central nervous system disease. • Strenuous physical activity performed within 48 hours before drug administration and during study. • Positive drug of abuse test and alcohol test. • Intake of gutka, pan and any other thing containing nicotine 48 hours before and during study. • Volunteer with thyroid dysfunction.

Age
From **18 years** old to **45 years** old

Gender
Male

Phase
4

Groups that have been masked
No information

Sample size
Target sample size: **10**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

1

Registry name
Iranian Registry of Clinical Trials (IRCT)

Secondary trial Id
CB-002-PEG-2010

Registration date
2012-01-16, 1390/10/26

Ethics committees

1

Ethics committee

Name of ethics committee
Independent Ethics Committee of International Center for Chemical and Biological Sciences (ICCBS); P

Street address
University of Karachi

City
Karachi

Postal code
75270

Approval date
2010-07-09, 1389/04/18

Ethics committee reference number
ICCBS/IEC/Lett-17/10

Health conditions studied

1

Description of health condition studied
Chronic viral hepatitis C

ICD-10 code
B18.2

ICD-10 code description
Viral Hepatitis

Primary outcomes

1

Description
Serum levels of peginterferon α-2a Pharmacokinetic parameters: Cmax, Tmax, AUC0-t, AUC0-∞, T1/2,

Timepoint
At 0, 1, 2, 3, 6, 12, 24, 36, 60, 84, 108, 132 and 156 hours

Method of measurement

• Serum concentration measured by Enzyme-linked immunosorbent assay (ELISA). • Pharmacokinetic (PK) parameter will be determined on the basis of measurement of concentration; performed by means of model independent method using Pk-solution and PPstat computer programs. • Elimination half-life (T1/2) calculated as 0.693 /k. • Area under the curve to the last measurable concentration (AUC) 0-t) will be calculated by the linear trapezoidal rule. Area under the curve extrapolated to infinity (AUCo-inf) will be calculated as AUC0-t + Ct /k, where Ct is the last measurable concentration.

Secondary outcomes

1

Description
Safety as measured by the frequency and intensity of adverse events (AEs), vital signs measurement, Lab tests: effect on neutrophils, total leukocytes count, absolute neutrophil counts, Hb levels, ALT levels.

Timepoint
Adverse events Monitoring: throughout study period (two weeks) Vital sign measurement: at time 0, 1, 2, 4, 8, 12, 24, 36, 60, 84, 108, 132, & 156hours. 0 to 156 hours Lab tests: within two weeks before drug administration (Baseline), on day five (during study) and day sixteen of drug administration (at follow up visit)

Method of measurement
By measuring the frequency and intensity of Standard Pharmacokinetic analysis of Serum level profileadverse event. For lab tests: comparing the day five and sixteen results with baseline results and calculated the p-value at 5% level of significance.

Intervention groups

1

Description
Peginterferon α-2a; 180 µg single dose; subcutaneously in abdominal region.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Center for Bioequivalence Studies and Bioassay Research

Full name of responsible person
Prof. Dr. Tasneem Ahmad

Street address
CBSBR at ICCBS University of Karachi

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
Manager Clinical Services/ B.Pharm

Other areas of specialty/work

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

City
Karachi

Province
Sind

Postal code
75300

Phone
009221-34972358

Fax

Email
ghousia@phaps.com

Web page address
www.phaps.com

Person responsible for scientific

inquiries

Contact

Name of organization / entity
Center for Bioequivalence Studies and Bioassay Research (CBSBR), International Center for Chemical a

Full name of responsible person
Prof. Dr. Tasneem Ahmad

Position
Ph.D.

Other areas of specialty/work

Street address
CBSBR at ICCBS, University of Karachi

City
Karachi

Province
Sind

Postal code
75300

Phone
009221-111222292

Fax

Email
tasneem.ahmed@iccs.edu

Web page address
www.iccs.edu

Person responsible for updating data

Contact

Name of organization / entity
Pharma Professional Services, Karachi, Pakistan

Full name of responsible person
Ms. Ghousia Saba

Position
Manager Clinical Services/ B.Pharm

Other areas of specialty/work

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

City
Karachi

Province
-Sind

Postal code
75300

Phone
00922134972358

Fax

Email
ghousia@phaps.com

Web page address
www.phaps.com

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