Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Efficacy of fluoroquinolones in treating interferon non-responders infected with HCV genotype 3a

Protocol summary

Summary

The study proposed here intends to evaluate the anti-HCV potential of fluoroquinolones on HCV-infected patients in a clinical trial, while taking into account the genotype differences relevant most to Pakistani population. We will focus on four fluoroquinolones that are found to be most potent in our in vitro experiments, and will explore the potential of these fluoroquinolones to inhibit HCV infection in Pakistani patients infected with genotype 3a. Fluoroquinolone drugs are already tested and approved for use on humans. They are commercially available and are commonly prescribed for the treatment of bacterial infections. The proposed study will help in identifying fluoroquinolones that may be used as a safer and inexpensive alternative to the current HCV treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014102619678N1**
Registration date: **2014-11-12, 1393/08/21**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2014-11-12, 1393/08/21

Registrant information

Name
Syed Hani Abidi
Name of organization / entity
Aga Khan University
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Pakistan
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Recruitment status

Recruitment complete

Funding source

Higher Education Commission, Pakistan Grant number: 20-2267

Expected recruitment start date

2015-01-01, 1393/10/11

Expected recruitment end date

2015-06-01, 1394/03/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of fluoroquinolones in treating interferon non-responders infected with HCV genotype 3a

Public title

Fluoroquinolones as anti-HCV drugs

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: •Patient on IFN treatment who have not shown two-log reduction in their HCV load for 3 months •HCV-RNA positive •Infection with HCV genotype 3a •Chronic hepatitis diagnosed by liver ultrasound •Pre-cirrhotic, as determined by liver ultrasound •Informed consent to participate in the study Exclusion criteria: •Known hypersensitivity to fluoroquinolones •Infection with HCV genotype other than 3a •Pregnant females •Concurrent hepatitis B or HIV infection •Carcinomatous changes on liver biopsy evident in liver ultrasound •History of alcohol or intravenous drug abuse •Disinclination to informed consent

Age
From **25 years** old to **60 years** old
Gender
Both

Phase
1
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Dow University of Health Sciences Institutional Review Board
Street address
Dow University of Health Sciences,
City
Karachi
Postal code
Approval date
2013-02-09, 1391/11/21
Ethics committee reference number
IRB-365/DUHS-2013

Health conditions studied

1

Description of health condition studied
Hepatitis C virus infection
ICD-10 code
B18.2
ICD-10 code description
Chronic viral hepatitis C

Primary outcomes

1

Description
Viral load
Timepoint
3 months post drug treatment
Method of measurement
Quantitative Real Time PCR for viral RNA

Secondary outcomes

1

Description
Liver function test and Complete Blood Count
Timepoint
Weekly throughout the drug treatment
Method of measurement
Clinical laboratory using automated testing units and microscopy

Intervention groups

1

Description
Intervention: Interferon therapy plus fluoroquinolone
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Qatar Hospital and Dow University of Health Sciences
Full name of responsible person
Dr Syed Ali/ Dr Syed Hani Abidi
Street address
City
Karachi

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Higher Education Commission, Pakistan
Full name of responsible person
Dr. Amjad Hussain
Street address
Research & Development Division, Higher Education Commission, Sector H-9, East Service Road
City
Islamabad
Grant name
Grant code / Reference number
20-2267
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Higher Education Commission, Pakistan

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
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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