

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

Country

Pakistan

Phone

+922134864496

Email address

syed.abidi@aku.edu

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*

Karachi

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74800

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Web page address**Person responsible for updating data****Person responsible for general inquiries****Contact****Name of organization / entity**

Aga Khan University

Full name of responsible person

Syed Hani Abidi

Position

Post-doctoral fellow/PhD

Other areas of specialty/work**Street address**

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City**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*