

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of oral Hydroxy Choloroquine on treatment of Generalized Vitiligo Vulgaris

Protocol summary

Study aim

The aim of this study was to evaluate the effect of oral hydroxychloroquine in the treatment of generalized vitiligo vulgaris

Design

quasi-experimental study (before and after) with single group design on 15 patients

Settings and conduct

This quasi-experimental study (before and after) on patients with generalized vulgaris vulgaris who referred to the dermatology clinic of Ghaem and Imam Reza (AS) hospitals and the dermatology clinic of 22 Bahman hospital who met the inclusion criteria was done. Fifteen patients were included in the study and their improvement rate was assessed based on the VASI score criterion.

Participants/Inclusion and exclusion criteria

Inclusion criterias Involvement of at least 10% of body surface At least one month has passed since the last treatment for the patient Not receiving any other treatment Not taking other drugs at the same time with immunomodulatory and immunosuppressive effects Over 7 years old Weight over 35 kg Do not take drugs that interfere with hydroxychloroquine, such as Artemether and Dapsone and Lumefantrine Exclusion criterias Glucose-6-phosphate dehydrogenase deficiency Retinopathy Sensitivity to antimalarial compounds Renal failure Psoriasis Myasthenia gravis Acute gastrointestinal disorders Hepatic failure

Intervention groups

HCQ was orally administered 400 mg daily (~6.5 mg/Kg of body weight) by 15 patients with generalized vitiligo for three months. Patients were evaluated monthly and skin re-pigmentation was assessed using the VASI.

Main outcome variables

Complications ; Extent and intensity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201212049690N1**

Registration date: **2020-12-28, 1399/10/08**

Registration timing: **retrospective**

Last update: **2020-12-28, 1399/10/08**

Update count: **0**

Registration date

2020-12-28, 1399/10/08

Registrant information

Name

soudabeh sazgarnia

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3761 5556

Email address

soodabe.sn@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-22, 1398/03/01

Expected recruitment end date

2020-08-31, 1399/06/10

Actual recruitment start date

2019-05-22, 1398/03/01

Actual recruitment end date

2020-08-31, 1399/06/10

Trial completion date

2020-08-31, 1399/06/10

Scientific title

Evaluation of oral Hydroxy Chloroquine on treatment of Generalized Vitiligo Vulgaris		Province Razavi Khorasan	
Public title Evaluation of Hydroxy Chloroquine on Generalized Vitiligo Vulgaris		Postal code 9185735386	
Purpose Treatment		Approval date 2019-04-17, 1398/01/28	
Inclusion/Exclusion criteria Inclusion criteria: Involvement of at least 10% of body surface At least one month has passed since the last treatment for the patient Not receiving any other treatment Not taking other drugs at the same time with immunomodulatory and immunosuppressive effects Over 7 years old Weight over 35 kg Do not take drugs that interfere with hydroxychloroquine, such as Image result for artemether and Dapsone and Lumfanterin Exclusion criteria: Glucose-6-phosphate dehydrogenase deficiency Retinopathy Acute gastrointestinal disorders Myasthenia gravis Psoriasis Renal failure Sensitivity to antimalarial compounds Hepatic failure		Ethics committee reference number IR.IAU.MSHD.REC.1398.020	
Age From 7 years old		Health conditions studied <u>1</u> Description of health condition studied Generalized Vitiligo vulgaris	
Gender Both		ICD-10 code L80	
Phase 2-3		ICD-10 code description Vitiligo	
Groups that have been masked No information		Primary outcomes <u>1</u> Description Score in Vasi Score	
Sample size Target sample size: 15 Actual sample size reached: 15		Timepoint Before starting treatment, one-two-three month after start using drug	
Randomization (investigator's opinion) N/A		Method of measurement Vasi Score	
Randomization description		Secondary outcomes empty	
Blinding (investigator's opinion) Not blinded		Intervention groups <u>1</u> Description Intervention group: HCQ was orally administered 400 mg daily (~6.5 mg/Kg of body weight) by 15 patients with generalized vitiligo for three months. Patients were evaluated monthly and skin re-pigmentation was assessed using the VASI SCORE.	
Blinding description		Category Treatment - Drugs	
Placebo Not used		Recruitment centers <u>1</u> Recruitment center Name of recruitment center Imam Reza Hospital	
Assignment Single		Full name of responsible person Soudabeh Sazgarnia	
Other design features		Street address Imam Reza Hospital, Imam Reza Sq.	
Secondary Ids empty		City Mashhad	
Ethics committees <u>1</u> Ethics committee Name of ethics committee Ethics committee of Islamic Azad University of Mashhad			
Street address 2nd Floor, No. 152, Nastaran 18 St, Malek Abad Blvd			
City Mashhad			

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Recruitment center
Name of recruitment center
Ghaem Hospital
Full name of responsible person
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Recruitment center
Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Saeed Abtahi
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Islamic Azad University
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Soudabeh Sazgarnia
Position
General Practitioner
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
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Person responsible for scientific inquiries

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Full name of responsible person
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professor

Latest degree

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data can be shared after patients are made
unidentifiable

When the data will become available and for how long

Data can be accessible 6 months after results are
published

To whom data/document is available

Data will be available for researchers in universities and
other scientific institutes

Under which criteria data/document could be used

Carrying out analysis on data is permitted

From where data/document is obtainable

Data can be accessible through sending an email to the
corresponding author

What processes are involved for a request to access data/document

After sending a request email to the corresponding
author, data will be sent in 1 month

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

Islamic Azad University

Full name of responsible person

Soudabeh Sazgarnia

Position

General practitioner

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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