Effect of hydroxychloroquine on COVID-19 prevention in cancer patients undergoing treatment: A structured summary of a study protocol for a randomised controlled trial.

Abolghasem Allahyari
Hossein Rahimi
Majid Khadem-Rezaiyan
Zahra Mozaheb
Mohsen Seddigh-Shamsi
Alireza Bary
Mostafa Kamandi
Sajad Ataei Azimi
Saeed Eslami HasanbAbadi
Alireza Noferesti
Somayeh Sadat Shariatmaghani
https://orcid.org/0000-0002-7178-7184
Houshang Rafatpanah
https://orcid.org/0000-0002-1061-5864
Shohreh Khatami
Afshin Jabbar Imani
Hassan Mortazi
Mohammad Moeini Nodeh (moeininm@mums.ac.ir)
Mashhad Unoversity of Medical Sciences https://orcid.org/0000-0002-3713-7671

Method Article

Keywords: COVID-19, Randomised controlled trial, protocol, Hydroxychloroquine, Acute Lymphoid Leukemia, Acute Myeloid Leukemia, Breast cancer, Colon cancer, Prophylaxis

DOI: https://doi.org/10.21203/rs.3.pex-969/v1

Abstract

This is a multi-center, two-arm, parallel-group, triple-blind, phase 2-3 randomised controlled trial. All patients over the age of 15 from 5 types of cancer, acute lymphoid and myeloid leukemias, non-Hodgkin's lymphoma, breast and colon cancer will enter the study. Patients are randomly assigned to two groups. During two months of treatment, the two groups are treated with either hydroxychloroquine or placebo. Patients will be monitored for COVID-19 symptoms. The primary end point of the study is to investigate the incidence of COVID-19 in patients.

Randomisation will be performed using randomly permuted blocks. The allocation ratio in two groups is 1:1. Participants, caregivers, outcome assessor and the data analyst are blinded to group assignment.

The calculated total sample size is 60 patients, with 30 patients in each group. The trial began on April 14, 2020 and recruitment is ongoing. Recruitment is anticipated to be completed by June 14, 2020. This trial has been registered on *the Iranian Registry of Clinical Trials* (IRCT) with the registration number of IRCT20200405046958N1.

Introduction

The new COVID-19 disease and its rapid spread have caused much concern in the community.

The unknown nature of the virus and the limited capabilities of the medical staff on the one hand and the higher susceptibility of cancer patients to this viral disease and higher mortality rate on the other hand have caused fear among physicians and cancer patients about continuing cancer treatment in the current situation.

Delayed treatment can in many cases lead to the progression of cancer and make the treatable disease incurable, or increase the side effects, and in some cases lead to death.

Reagents

Hydroxychloroquine tablet (Amin® Pharmaceutical Company, Isfahan, Iran) and placebo (identical in terms of shape, color, smell and taste)

Equipment

Not applicable.

Procedure

Patients are randomly assigned to two groups; one being given hydroxychloroquine and the other is given placebo. During two months of treatment, the two groups are treated with either hydroxychloroquine or placebo as a single 200 mg tablet every other day. Patients will be monitored for COVID-19 symptoms

during the follow-up period. If signs or symptoms occur (fever, cough, shortness of breath), they will be examined and investigated with a high-resolution computed tomography (CT) scan of the lungs, COVID-19 specific IgM, IgG antibody assay and a nucleic acid amplification test (NAT) for the SARS-CoV-2 virus.

Troubleshooting

Problem

1- Failure to take regular medication.

2- Failure to follow other health instructions by participants to prevent the virus.

3- Inconclusive diagnosis

Possible reason

1- Chemotherapy induced Nausea & Vomiting.

2- Social, cultural, economic reasons.

3- Symptomatic patients that are negative for repeated their serological and nucleic acid tests. (False negative)

Solution

1- Complete/maximum control of nausea and vomiting with the help of supportive therapies and tracking drug use by phone calls.

2- Mention preventive instructions face to face with the patient and his/her family at each visit.

3-

A) If a CT scan confirms COVID-19 disease, it is considered a suspected COVID-19 diagnosis.

B) If the CT scan findings are not in favor of COVID-19, the patient will not be considered COVID-19.

Time Taken

2 month for recruiting and 2 month for follow up of each patient.

Anticipated Results

We think that Hydroxychloroquine can reduce the incidence of COVID-19 in cancer patients.

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Acknowledgements

We thank the Vice Chancellor for Research of Mashhad University of Medical Sciences for supporting this project. Also, the help of Clinical Research Development Unit of Akbar Hospital (affiliated to Mashhad University of Medical Sciences, Mashhad, Iran) in designing the study and methodological issues is highly appreciated.