Clinical Trial Protocol
Iranian Registry of Clinical Trials
10 Oct 2022

The effects of Rosuvastatin in Expression of Tim-3 on NK cells and NKT cells in Patients with Chronic Hepatitis B by Flow cytometry

Protocol summary

Study aim
The effects of Rosuvastatin in Expression of Tim-3 on NK cells and NKT cells in Patients with Chronic Hepatitis B by Flow cytometry

Design
Clinical trial with control and parallel group, double-blind, phase IV, simple randomization, sample size: 30

Settings and conduct
Patients with chronic hepatitis B, aged 20-50 years, referred to specialized clinics of Golestan University of Medical Sciences after obtaining informed consent. Patients are matched for age, sex, and other treatment protocols they use, and then classified into two groups. Patients are given Rosuvastatin 20mg/day with food for a period of three months that 15 patients received placebo and 15 patients received Rosuvastatin. The physician and the patient are not aware of the type of drug delivered to groups A and B. After three months, the resident took 5cc of blood from patients at sayyad hospital and immediately transferred to the laboratory at ambient temperature. Then, TIM3 expression tests have performed at laboratory of school of advanced medical technology.

Participants/Inclusion and exclusion criteria
Entry requirements: Patients with Chronic Hepatitis B, Age range 20-50 years Non-qualified requirements: Patient's unwillingness to continue participating in the study, Acute kidney failure and dialysis, Immune system disorders, Malignancies, Use of Immunosuppressive drugs, Surgery over the past 3 months, Statin Allergy, Alcohol and drug addiction... , Pregnancy, Inability to visit the clinic, Cirrhosis.

Intervention groups
Intervention group: 15 Patients with hepatitis B received Rosuvastatin 20 mg/day from Abidi pharmaceutical company with food for a period of three months. Control group: 15 Patients with hepatitis B received placebo from the same company with food for a period of three months.

Main outcome variables
The percentage of NK cells containing Tim3 Protein, The percentage of NKT cells containing Tim3 Protein

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: IRCT20190602043789N1
Registration date: 2019-10-13, 1398/07/21
Registration timing: prospective

Last update: 2019-10-13, 1398/07/21
Update count: 0

Registration date
2019-10-13, 1398/07/21

Registrant information
Name
shohreh taziki
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 17 3245 2651
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dr_sh_taziki@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-10-23, 1398/08/01

Expected recruitment end date
2019-11-22, 1398/09/01

Actual recruitment start date
empty

Actual recruitment end date
Scientific title
The effects of Rosuvastatin in Expression of Tim-3 on NK cells and NKT cells in Patients with Chronic Hepatitis B by Flow cytometry

Public title
Effect of Rosuvastatin in Expression of Tim-3

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with Chronic Hepatitis B Age range 20-50 years

Exclusion criteria:
Patient's unwillingness to continue participating in the study Acute kidney failure and dialysis Immune system disorders Malignancies Use of Immunosuppressive drugs Surgery over the past 3 months Statin Allergy Alcohol and drug addiction... Pregnancy Inability to visit the clinic Cirrhosis

Age
From 20 years old to 50 years old

Gender
Both

Phase
4

Groups that have been masked
- Participant
- Investigator
- Data analyser

Sample size
Target sample size: 30

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization method: Simple randomization Unit of Randomization: Individual Randomization tool: Sealed envelope

Blinding (investigator's opinion)
Double blinded

Blinding description
For blinding technique, the study groups are marked with the letters A and B, and these letters are marked on the sealed envelopes. The physician and the patient are not aware of the type of drug delivered to groups A and B, and only the pharmacist who supplied the drug to the patient is aware of its content. The results are also reported to the data analyser by grouping A and B.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Golestan University of Medical Sciences

Street address
Golestan University of Medical Science, Hirkan Blvd

City
Gorgan

Province
Golestan

Postal code
4934174515

Approval date
2019-01-06, 1397/10/16

Ethics committee reference number
IR.GOUMS.REC.1397.342

Health conditions studied

1

Description of health condition studied
Chronic Hepatitis B

ICD-10 code
B18.1

ICD-10 code description
Chronic viral hepatitis B without delta-agent

Primary outcomes

1

Description
The percentage of NK cells containing Tim3 Protein

Timepoint
Three Months after taking Rosuvastatin Tablets

Method of measurement
By kit in blood samples

2

Description
The percentage of NKT cells containing Tim3 Protein

Timepoint
Three Months after taking Rosuvastatin Tablets

Method of measurement
By kit in blood samples

Secondary outcomes
empty

Intervention groups

1

Description
Intervention group:15 Patients with hepatitis B received
Rosuvastatin 20 mg/day from Abidi pharmaceutical company with food for a period of three months.

Category
Treatment - Drugs

Description
Control group: 15 Patients with hepatitis B received placebo from Abidi pharmaceutical company with food for a period of three months.

Category
Placebo

Recruitment centers

1
Recruitment center
Name of recruitment center
Sayyad Medical and Educational Center
Full name of responsible person
Ali Najafi
Street address
Sayyad Medical and Educational Center, Sayyad Blvd
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Sponsors / Funding sources

1
Sponsor
Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
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Title of funding source
Gorgan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Country of origin
empty
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
Shohreh Taziki
Position
Assistant professor
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Sharing plan
Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Only part of the data, such as information about the original outcome, can be shared.
When the data will become available and for how long
After the article is published, the results can be presented.
To whom data/document is available
Data will be available only to researchers working in academic and scientific institutions.
Under which criteria data/document could be used
The data is only visible to other researchers.
From where data/document is obtainable
Vice-chancellor for Research and Technology
What processes are involved for a request to access data/document
Written Request by Applicant University to Department of Research and Technology of Golestan University of Medical Sciences
Comments