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 Resovastatin. 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 3cc 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 status
Recruitment complete

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 analyzer 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.

**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
City
Gorgan
Province
Golestan
Postal code
4917867439
Phone
+98 17 3220 2291
Email
infosayyad@goums.ac.ir

**Sponsors / Funding sources**

1

**Sponsor**
Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
Dr.Mohammadreza Honarvar
Street address
Sayyad Medical and Educational Center, Sayyad Blvd
City
Gorgan
Province
Golestan
Postal code
4917867439
Phone
+98 17 3220 2291
Email
dr_sh_taziki@yahoo.com

**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**

**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
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
Golestan University of Medical Science, Hirkan Blvd
City
Gorgan
Province
Golestan
Postal code
4934174515
Phone
+98 17 3245 1434
Fax
Email
dr_sh_taziki@yahoo.com

**Person responsible for scientific inquiries**

Contact
Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
Shohreh Taziki
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
Golestan University of Medical Science, Hirkan Blvd
City
Gorgan
Province
Golestan
Postal code
Person responsible for updating data

Contact
- Name of organization / entity: Gorgan University of Medical Sciences
- Full name of responsible person: Seyedeh Rozhin Hosseini
- Position: Supervisor of Research and Development Office
- Latest degree: Medical doctor
- Other areas of specialty/work: Medical Pharmacy

Street address
- Golestan University of Medical Science, Hirkan Blvd

City
- Gorgan

Province
- Golestan

Postal code
- 4934174515

Phone
- +98 17 3191 2539

Fax
- dr_sh_taziki@yahoo.com

Email
- dr_sh_taziki@yahoo.com

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