Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

IMPACT OF GENETIC POLYMORPHISM OF ROSUVASTATIN TRANSPORTER GENES ON ITS PLASMA LEVELS AND LIPID LOWERING EFFICACY IN HYPERLIPIDEMIC PAKISTANI PATIENTS

Protocol summary

Study aim
To explore single nucleotide polymorphisms of transporter target genes of rosuvastatin SLCO1B3 and ABCG2

Design
One arm/group quasi-experimental clinical trial, non-randomized, non-blinded design of 384 patients enrolled between December 2022 to December 2023.

Settings and conduct
Pharmacology Department of Army Medical College, National University of Medical Sciences. Rawalpindi. Tertiary Care Hospital, Islamabad.

Participants/Inclusion and exclusion criteria
LDL-c > 130 mg/dL

Intervention groups
Patients will receive rosuvastatin once a day for 12 weeks. So intervention will be done with rosuvastatin administration . Blood sampling for biochemical analysis will be done at day 0 and after 12 weeks of intervention with rosuvastatin. Genotyping will be done by Polymerase Chain Reaction-Restriction Fragment Length Polymorphism (PCR-RFLP) and Allele Specific Polymerase Chain Reaction (AS-PCR) and plasma rosuvastatin levels will be determined by High Performance Liquid Chromatography (HPLC) after follow up period of 12 weeks

Main outcome variables
i.Polymorphic alleles of rosuvastatin transporter genes SLCOIB3 & ABCG2 ii Plasma rosuvastatin levels iii. Lipid Profile iv. Creatine Phospho Kinase v. Liver &Renal Function Tests vi. C-Reactive Protein

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221127056625N1**
Registration date: **2022-12-22, 1401/10/01**
Registration timing: **registered_while_recruiting**

Last update: **2022-12-22, 1401/10/01**
Update count: **0**

Registration date
2022-12-22, 1401/10/01

Registrant information

Name
Mahjabeen Sharif

Name of organization / entity
National University of Medical Sciences Rawalpindi

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Pakistan

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+92 333 5077896

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mahjabeen30@hotmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-12-05, 1401/09/14

Expected recruitment end date
2023-12-05, 1402/09/14

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
IMPACT OF GENETIC POLYMORPHISM OF ROSUVASTATIN TRANSPORTER GENES ON ITS PLASMA LEVELS AND LIPID

LOWERING EFFICACY IN HYPERLIPIDEMIC PAKISTANI PATIENTS

Public title
Genetic Polymorphism of Rosuvastatin
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Both males and females belonging to different Pakistani regions Age 30-70 years Patients with elevated LDL-c levels more than 130 mg/dL (3.4 mmoles/L) Patients with normal serum CPK levels 10-120 mcg/dL
Exclusion criteria:
Patients taking antihyperlipidemic drugs other than rosuvastatin Hepatic and kidney diseases Patients with raised serum CPK levels >120 mcg/dL Concurrent use of potent cytochrome inducer or inhibitor with documented interaction with rosuvastatin Pregnant and nursing females . Hypersensitivity to rosuvastatin
Age
From **30 years** old to **70 years** old
Gender
Both

Phase
4
Groups that have been masked
No information
Sample size
Target sample size: **384**
More than 1 sample in each individual
Number of samples in each individual: **1**
Each individual will provide one sample for the study. Patients fulfilling the inclusion criteria will be enrolled for this study. Informed consent will be taken from every patient. Study will be conducted in one arm. Patients will receive rosuvastatin once a day for 12 weeks. After taking brief history, demographic data will be recorded. Blood sampling for biochemical analysis (total lipid profile, serum creatine phosphokinase, liver function tests, renal function tests, thyroid stimulating hormone , C-reactive protein and glycosylated haemoglobin) will be done at day 0 and after 12 weeks of intervention with rosuvastatin. Genotyping will be done by Polymerase Chain Reaction-Restriction Fragment Length Polymorphism (PCR-RFLP) and Allele Specific Polymerase Chain Reaction (AS-PCR) and plasma rosuvastatin levels will be determined by High Performance Liquid Chromatography (HPLC) after follow up period of 12 weeks (Song et al., 2022).
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features
This will be a quasi experimental clinical trial in which there will be intervention with rosuvastatin in hyperlipidemic Pakistani patients but there will be no randomization.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical Review Committee of Army Medical College (AMC) Rawalpindi
Street address
B-342/15 street No:3 Lane No:4 Peshawar Road Rawalpindi
City
Rawalpindi
Postal code
46000
Approval date
2022-08-25, 1401/06/03
Ethics committee reference number
ERC/ID/230

Health conditions studied

1

Description of health condition studied
Patients of hyperlipidemia with LDLc> 130mg/dL
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Prevalence of genetic polymorphism of rosuvastatin transporter genes SLCO1B3 and ABCG2 for their variant alleles i.e. SLCOIB3 334T >G (rs4149117), 699 G>A (rs7311358) and ABCG2 421 C>A (rs2231142), 34G >A (rs2231137)
Timepoint
After 12 weeks of intervention with rosuvastatin drug
Method of measurement
Polymerase Chain Reaction-Restriction Fragment Length Polymorphism (PCR-RFLP) and Allele Specific Polymerase Chain Reaction (AS-PCR)

Secondary outcomes

1

Description
Plasma rosuvastatin levels
Timepoint

After 12 weeks of intervention with rosuvastatin

Method of measurement

High Performance Liquid Chromatography (HPLC)

2

Description

Impact of polymorphic alleles of rosuvastatin transporter genes on biochemical parameters like Lipid Profile (TC, LDL-c, HDL-c, TG and VLDL) ii. Serum Creatine Phospho Kinase (CPK) iii. Liver Function Tests iv. Renal Function Tests v. C-Reactive Protein (CRP)

Timepoint

After 12 weeks of intervention with rosuvastatin

Method of measurement

Biochemical analysis

Intervention groups

1

Description

Intervention group: Patients will receive rosuvastatin once daily for a period of 12 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tertiary Care Hospital Islamabad

Full name of responsible person

Dr. Mahjabeen Sharif

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B-342/15 street No:3 Lane No:4 peshawar road Rawalpindi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

National University of Medical Sciences (NUMS) Rawalpindi

Full name of responsible person

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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

National University of Medical Sciences (NUMS) Rawalpindi

Proportion provided by this source

20

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

Army Medical College Rawalpindi, National University of Medical Sciences (NUMS) Rawalpindi

Full name of responsible person

Dr. Mahjabeen Sharif

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
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Position
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Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
there is no further information
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
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
Study protocol
When the data will become available and for how long
06 months after publication
To whom data/document is available
for academic institutions
Under which criteria data/document could be used
by research articles
From where data/document is obtainable
mahjabeen30@hotmail.com
What processes are involved for a request to access data/document
through mail
Comments
None