

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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 SLCO1B3 & 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

Country

Pakistan

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+92 333 5077896

Email address

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 mmol/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 <i>No information</i> 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. SLCO1B3 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
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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

Street address

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

Mahjabeen Sharif

Street address

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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 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