Trials

STUDY PROTOCOL

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Efficacy, safety and cost-effectiveness of 40 mg versus 80 mg atorvastatin in a Sri Lankan cohort with acute coronary syndrome: a protocol for a single-centre randomised controlled clinical trial

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Abstract

Background Most guidelines recommend high-intensity statins for the secondary prevention of acute coronary syndrome (ACS). However, several studies from other Asian populations suggest enhanced sensitivity to statins, with effective low-density lipoprotein cholesterol (LDL-C) reduction seen at lower doses and possible higher incidence of adverse effects at higher statin doses. However, there is no published data from Sri Lanka. Therefore, we aimed to explore this hypothesis by comparing the efficacy, safety and cost-effectiveness of atorvastatin at doses of 40 mg and 80 mg in a cohort of South Asian individuals presenting with ACS from Sri Lanka.

Methods This single-centre, prospective, randomised, controlled, open-label clinical trial is being conducted among patients naïve for statins admitted with incident ACS to a tertiary care setting in Sri Lanka. All patients will have LDL-C measured at baseline and are randomised to receive atorvastatin 40 mg or 80 mg in addition to standard of care. Data are collected using an interviewer-administered proforma. Patients are evaluated at 6, 12 and 24 weeks for adverse drug reactions and LDL-C level. The primary endpoint is the percentage of patients achieving LDL-C ≤ 70 mg/dL at 12 weeks. This outcome will be analysed by the intention-to-treat analysis. Secondary outcomes include safety assessments and a cost-effectiveness evaluation. For the latter, data on medication costs, including the number of tablets consumed, will be collected to calculate the average cost-effectiveness ratio and incremental cost-effectiveness ratio between the two dosing regimens.

Discussion This will be the first head-to-head comparison of atorvastatin 40 mg and 80 mg in a South Asian cohort. The findings will provide evidence on efficacy and safety of prescribing atorvastatin 40 mg dose in South Asians with ACS.

Trial registration Sri Lanka Clinical Trial Registry, SLCTR/2023/003. Registered on 03 March 2023, https://slctr.lk/trials/slctr-2023-003.

Keywords Atorvastatin, South Asia, Acute coronary syndrome, LDL-C, Dyslipidaemia

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Background

Acute coronary syndrome (ACS) is the leading cause of death worldwide [1], with a rising prevalence in South Asia [2, 3]. Once ACS is diagnosed, patients must adhere to secondary prevention strategies to reduce mortality risk, with a key objective being the reduction of low-density lipoprotein cholesterol (LDL-C) levels to less than or equal to 70 mg/dL (1.8 mmol/L) [4–6]. Statins are the first-line therapy used to achieve this goal. In Sri Lanka, atorvastatin is the most commonly used statin in state hospitals [7].

Most Western guidelines recommend high-intensity statins for the secondary prevention of ACS [8]. However, pharmacokinetic, pharmacogenomic and emerging clinical evidence from Asian populations suggests that lower doses may be equally effective in South Asians [9]. Liao showed increased plasma statin levels in Asians when compared with Caucasians [10] and Ranasinghe et al. further identified variants such as *SLCO1B1* and *ABCG2* in Sri Lankans which may predispose to statin-induced myopathy [11]. A recent randomised controlled trial conducted in Korea compared atorvastatin 10 mg versus 20 mg in high-risk patients and demonstrated comparable efficacy and safety profiles at both doses [12]. Additionally, a Japanese phase I/IIa trial in a cardiovascular cohort showed that atorvastatin at moderate doses achieved LDL-C lowering with good tolerability, reinforcing the relevance of lower dosing in Asian populations [13]. Although no clinical trial data are yet available from Sri Lanka, these evidences strongly support the rationale for conducting an exploratory, hypothesis-generating trial comparing 40 mg and 80 mg atorvaststin doses in our population.

A statin dose which can reduce the baseline LDL-C by 50% is considered a high-intensity statin [14] and atorvastatin 80 mg as well as 40 mg is considered a high-intensity statin dose. Higher doses are associated with an increased risk of both dose-related and non-dose-related adverse effects [15–17]. In Sri Lanka, where the healthcare system provides medications free of charge, optimising statin dosing is crucial for resource allocation. According to the State Pharmaceuticals Corporation, the cost of a 10 mg atorvastatin tablet is LKR 2.65 [18]. Therefore, an 80 mg daily dose (eight 10 mg tablets) costs LKR 21.20 per day, while a 40 mg dose (four 10 mg tablets) costs LKR 10.60 per day. This represents a 50% reduction in medication cost per patient. Considering the large number of patients requiring long-term statin therapy, these savings could significantly reduce the financial burden on the healthcare system. This study aims to establish scientific evidence for the efficacy, safety and cost-effectiveness of using 40 mg of atorvastatin, compared with 80 mg, as a secondary preventive measure for cardiovascular diseases in ACS patients.

Objectives

To compare the efficacy, safety and cost-effectiveness of atorvastatin doses (80 mg vs 40 mg) in lowering the LDL-C levels to the target, among patients with ACS.

Hypothesis

In South Asian patients experiencing incident ACS, a daily dose of 40 mg of atorvastatin is adequate, safer and more cost-effective in achieving the target LDL-C level of $\leq$70 mg/dL than a dose of 80 mg.

Method and design

This proposal was developed in accordance with the National Institute for Health and Care Excellence (NICE) guideline recommendations on lipid modification therapy for cardiovascular disease prevention and cholesterol clinical practice guidelines by the American Heart Association (AHA) 2018 [4–6].

Trial design

This study is an ongoing single-centre, randomised, controlled clinical trial. This study employs an open-label design due to practical considerations within the Sri Lankan healthcare context. This study will evaluate the efficacy, safety and cost-effectiveness of atorvastatin 40 mg compared with 80 mg as a secondary preventive measure in South Asian patients with ACS.

Study setting

This study is conducted at the University Medical Unit of Colombo North Teaching Hospital, Ragama, Sri Lanka.

Study population and eligibility criteria

All consenting patients above 18 years of age with incident ACS admitted to the medical casualty ward of the University Medical Unit, Colombo North Teaching Hospital, Ragama, are screened.

Inclusion criteria

- Male or female patients aged 18 years or older
- Patients presenting with incident ACS as defined by the American Heart Association/American College of Cardiology (AHA/ACC) guidelines in 2014, based on clinical presentation, history, electrocardiogram (ECG) and cardiac biomarkers [19]

    a. STEMI—Patients with ST elevation detected on ECG who require any form of reperfusion therapy (thrombolysis, percutaneous coronary intervention (PCI) or emergency coronary artery bypass grafting (CABG))

b. NSTEMI—Patients presenting with a clinical history suggestive of a chest pain of cardiac origin with or without ECG changes compatible with ACS (ST depression, transient ST elevation or new T-wave inversions) and elevated cardiac troponin levels (value above the 99th percentile of the upper reference level)
c. Unstable angina (UA)—Patients presenting with a clinical history suggestive of a chest pain of cardiac origin with or without ECG changes compatible with ACS (ST depression, transient ST elevation or new T-wave inversions) and non-elevated cardiac troponin levels

- Patients with the ability to understand and follow study-related instructions
- Patients providing written informed consent

Exclusion criteria

- Patients with familial hypercholesterolemia (previously identified patients and patients screened using the Simon-Broome criteria [20]).
- Patients diagnosed with diabetes mellitus (DM) at the screening visit. DM is associated with altered lipid metabolism, including increased triglycerides and decrease high-density lipoprotein cholesterol (HDL-C) level, which can affect statin pharmacodynamics and the assessment of LDL-C reduction attributable solely to statin therapy.
- Patients diagnosed with chronic kidney disease (CKD) at the screening visit. CKD, particularly with albuminuria, leads to significant changes in lipoprotein metabolism, such as elevated triglycerides and modified HDL composition, which can influence response to statins and affect the Friedewald calculation for LDL-C estimation.
- Patients who are already on statin therapy.
- Patients with known hypersensitivity to the study treatment.
- Patients receiving concomitant treatment with cytochrome P450 3A4 (CYP3A4) inhibitors.
- Pregnant or lactating mothers.
- Any other condition or therapy that would make the patient unsuitable for this study or would not allow participation for the full planned study period (e.g. active malignancy or other conditions limiting life expectancy to < 12 months).

Sample size

The sample size of this study was determined on the basis of non-inferiority trails, on an anticipated response rate of 47% in the group receiving 40 mg of atorvastatin, as reported in a prior study in India [21]. The calculated minimal sample size was 70 patients with 35 patients in each of the intervention and control groups, considering a type I error of 0.05 and a power of 80%. Accounting for a potential 10% dropout rate, the study aims to recruit a total of 78 patients.

Subject enrolment and randomisation

Researchers visit the University Medical Unit on 'day 0' to identify patients presenting with incident ACS who meet the eligibility criteria. Each eligible patients are provided with a patient information sheet in their preferred language and given the opportunity to clarify any doubts with the study investigators. Informed written consent is obtained prior to enrolment.

Following recruitment, an interviewer-administered questionnaire is completed to collect data on socio-demographic background, past medical history and family history. Anthropometric measurements, including height, weight and waist circumference, are also recorded.

Once a physician confirms the indication for high-intensity statin therapy, patients are randomised into either the intervention group (receiving 40 mg atorvastatin daily) or the control group (receiving 80 mg atorvastatin daily, in accordance with NICE guidelines). Randomisation is carried out using a computer-generated random number sequence. Each allocation will be sealed in an opaque, sequentially numbered envelope. After eligibility is confirmed and consent is obtained, the patient selects one envelope, which determines their assigned dosage. This process ensures allocation concealment and minimises selection bias (Fig. 1).

Participant timeline

The schedule of enrolment, intervention allocation, assessments, and follow-up is summarized in the SPIRIT figure below (Fig. 2.)

Intervention

Patients in the intervention group receives oral atorvastatin at dose of 40 mg, whereas patients in the control group receives atorvastatin at a daily dose of 80 mg. All other standard medical treatment including the routine management provided to patients with ACS as per local and international clinical guidelines will continue. Patients who require interventions, including PCI, emergency CABG or thrombolysis and other cardiac procedures, receive them as per clinical indications and commenced on dual antiplatelet therapy along with the statin as well as anti-anginal medications, beta blockers, angiotensin converting enzyme (ACE) inhibitors and

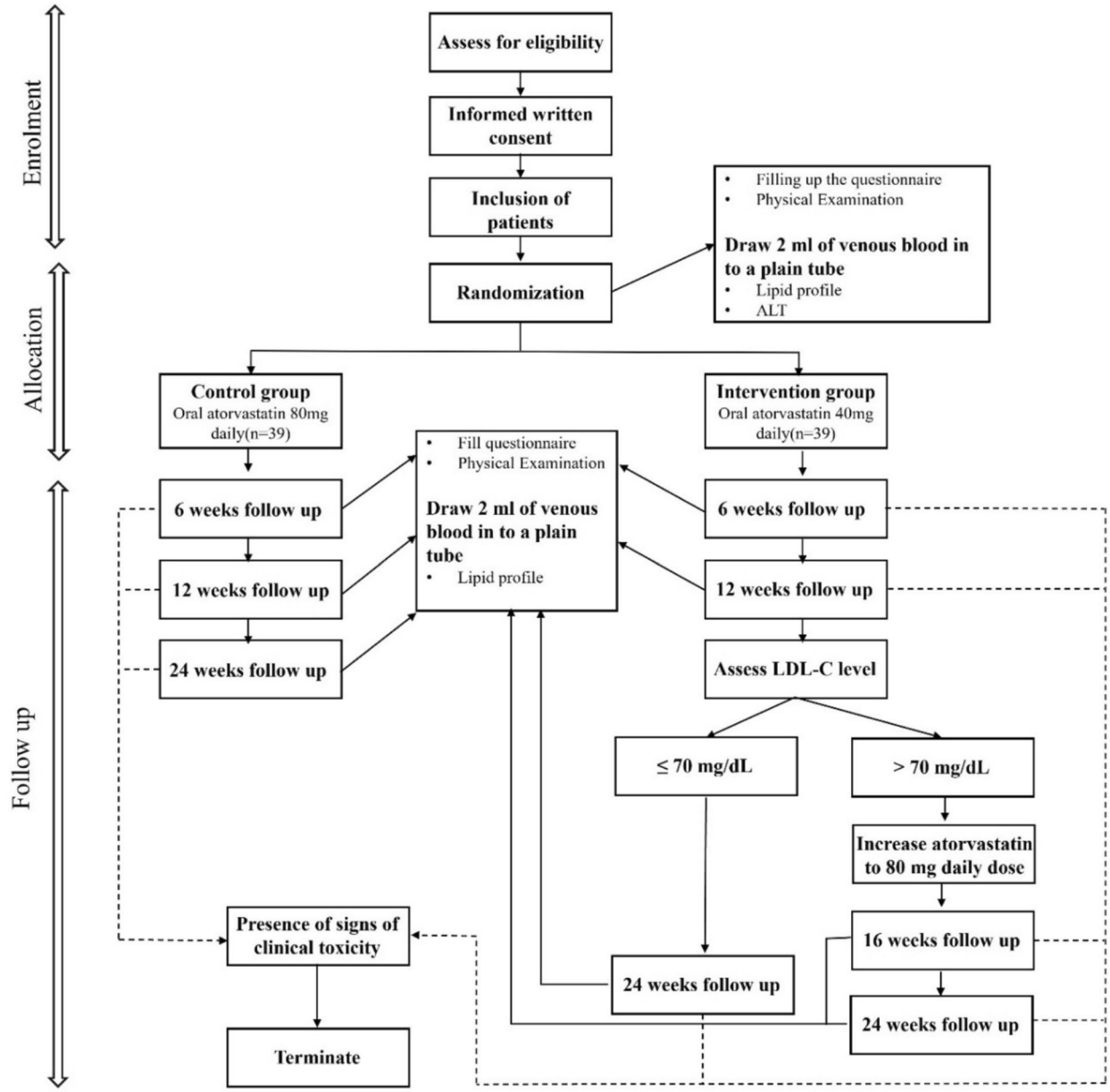

Fig. 1 Study design of the project (abbreviations: ALT, alanine transaminase; LDL-C, low-density lipoprotein cholesterol)

angiotensin receptor blockers (ARBs) depending on the clinical circumstances, in addition to advice on lifestyle modification (Fig. 2). Patients who undergo PCI with stent placement as well as emergency CABG will remain in the study.

Study procedure

Clinical evaluation

All patients are reviewed at enrolment by a consultant physician to determine their suitability for high-intensity statin therapy. Following randomisation and initiation of the assigned atorvastatin dose, these patients are reviewed at the medical clinic of Colombo North Teaching Hospital at 6, 12 and optionally 16 weeks, with a final review at 24 weeks (Fig. 1). During each review visit, a trained medical officer completes the questionnaire to assess drug adherence, current medical status and any previously unknown adverse effects associated with atorvastatin. A comprehensive physical examination is performed to assess the health status, to evaluate tolerance and to detect any adverse effects of the medication. This examination includes measurements of body mass

	STUDY PERIOD							
	Enrolment	Allocation	Post-allocation					Close-out
TIMEPOINT**	*0*	0	T_{6weeks}	$T_{12weeks}$	$T_{16weeks}$	$T_{24weeks}$	*etc.*	t_x
ENROLMENT:								
Eligibility screen	X							
Informed consent	X							
Allocation		X						
INTERVENTIONS:								
[Atorvastatin 40mg group]			←	—	—	→		
[Atorvastatin 80mg group]			←	—	—	→		
ASSESSMENTS:								
Initial lipid profile, anthropometry		X						
Lipid profile, clinical evaluation			X	X	X	X		X
Safety profile assessment			X	X	X	X		X

Fig. 2 SPIRIT figure highlighting the timeline of the study

index (BMI), blood pressure and other relevant clinical parameters.

Laboratory evaluation

At enrolment, a baseline venous blood sample is drawn from each patient to evaluate the lipid profile, including total cholesterol, HDL-C, LDL-C and triglyceride, and alanine transaminase (ALT) levels. Lipid profiles are subsequently measured at each clinic visit at 6, 12, 16 and 24 weeks. In the event of any adverse effects, ALT and creatine phosphokinase (CPK) levels are assessed as needed.

Lipid profiling is performed under 12 hour fasting conditions. The first sample at enrolment is drawn within 24 hours of the onset of chest pain, as recommended [22]. Total cholesterol, HDL-C and triglycerides is analysed via enzymatic colorimetric methods via a Mindray BA-88A semi-automated chemistry analyser (Shenzhen Mindray Biomedical Electronics Co. Ltd., China). Internal quality control is maintained at two levels: level 1 for the physiological range and level 2 for the pathological range, with EXATROL quality control materials supplied by BIOLABO SAS, France. The laboratory participates in the National External Quality Assurance Scheme (NEQAS) of Sri Lanka, which is administered by the Medical Research Institute, Colombo. LDL-C is calculated via the Friedewald equation [23], and non-HDL-C is determined by subtracting HDL-C from total cholesterol.

Safety evaluation

During follow-up visits at 6, 12, 16 (optional) and 24 weeks, patients are interviewed by a trained medical officer to monitor for both known and unknown adverse effects associated with atorvastatin treatment. The potential adverse effects include hepatitis, myositis, myalgia and gastric discomfort. If any signs of toxicity are observed, patients are admitted to the University Medical Unit, Colombo North Teaching Hospital, Sri Lanka, for further management and monitoring, and ALT and CPK levels are assessed. These patients are withdrawn from the study. Per protocol analysis is used to analyse the safety profile.

All participants are provided with contact information of the investigators to clarify any queries regarding the trial and to report any suspected adverse effects throughout the study.

Cost-effectiveness evaluation

The total amount of money spent for medication is calculated separately for both arms. The mean cost of medication to achieve the targeted LDL-C level is compared between the two groups. The 'effectiveness' is measured from the health benefit achieved (the number of patients who reached the target LDL-C reduction within 12 weeks). The average cost-effectiveness ratio and incremental cost-effectiveness ratio are calculated.

Medication adherence monitoring and management

To ensure accurate assessment of the intervention's efficacy and safety, a multifaceted approach is implemented to monitor and promote medication adherence:

- Pill counts: At each clinic visit, remaining tablets are counted to objectively assess adherence. While pill counts are commonly used, they may overestimate adherence if used alone; therefore, they are complemented by additional strategies.
- Medication diaries: Participants receive a daily medication diary to record each dose taken. This self-reporting tool serves as a daily reminder and facilitates discussion during follow-up visits.
- Regular follow-up calls: Biweekly telephone calls are made to reinforce adherence, address any concerns and provide support.

Management of non-adherence

If a participant misses medication for less than seven consecutive days, they receive counselling to reinforce adherence and will remain in the study. If non-adherence exceeds seven consecutive days, or if there are two or more episodes of non-adherence of any duration, the participant is excluded from the study.

Outcome measures

Primary outcome

A reduction in LDL-C levels to less than or equal to 70 mg/dL at 12 weeks is the primary outcome.

Secondary outcomes

1. Percentage reduction of LDL-C from baseline
2. Non-HDL-C reduction at 12 and 24 weeks
3. Safety profile and adverse effects of treatment
4. Cost-effectiveness of the treatment

Data management and analysis

Data management

All collected data is anonymised and kept confidential. Questionnaires and laboratory reports are securely stored in locked cabinets, accessible only to the investigators. Personal identification details remain confidential and are not disclosed. Blood samples are destroyed after analysis and will not be used for any additional testing. The electronic database is maintained as a password-protected file. All the information will be disseminated solely through publication.

Statistical analysis

Data will be analysed using SPSS version 26. Categorical variables will be summarised as frequencies and percentages, while continuous variables will be reported as mean (standard deviation) or median (interquartile range), depending on the distribution. The Shapiro–Wilk test will be used to assess normality.

The primary endpoint—proportion of patients achieving LDL-C $\leq$ 70 mg/dL at 12 weeks—will be analysed using the intention-to-treat approach, including all randomised participants regardless of adherence. Secondary outcomes, including adverse events (safety profile), will be analysed using a per-protocol analysis.

Non-parametric tests will be applied where appropriate:

- Mann–Whitney U test for comparing categorical variables such as LDL-C levels between groups
- Chi-square test or Fisher's exact test for comparing categorical variables such as incidence of adverse events
- Wilcoxon signed-rank test for within-group comparisons of continuous variables over time

All statistical tests will be conducted at a 5% two-sided significance level. Comparative outcomes will be summarised with 95% confidence intervals and reported in accordance with the CONSORT guidelines.

Cost-effectiveness analysis

The total cost of medication will be calculated separately for each arm. Effectiveness will be measured by the number of patients achieving the LDL-C target within 12 weeks. We will calculate:

$$\textit{Average cost effectiveness } (ACER) = {}^{\textit{Net cost}}/_{\textit{Net health benefit}}$$

$$\textit{Incremental cost effectiveness ratio}(ICER) = {}^{\textit{Difference in costs } (A-B)}/_{\textit{difference in benefits } (A-B)}$$

This analysis will help evaluate the economic impact of the two dosing strategies within a resource-limited healthcare system.

Monitoring

Data monitoring

Data monitoring is carried out solely by the investigators. Funding authority is not involved in the monitoring at any point. Investigators have no competing interests to declare.

Harms

Intervention-related adverse effects are reviewed at each visit by a trained medical officer.

Ethical considerations

All patient management decisions are made by the clinical management team of the University Medical Unit in accordance with the unit's protocols. Patients who experience severe adverse events, whether related or unrelated to the treatment, or those who cannot tolerate atorvastatin, are discontinued from the study. Suspected adverse events are reported according to the national guidelines for adverse event reporting. The reports are submitted in the specified format to the director of medical technology and supplies at the National Medicines Regulatory Authority of Sri Lanka, and to the Adverse Drug Reaction Monitoring Unit of the Department of Pharmacology, Faculty of Medicine, University of Colombo. Participants have the right to withdraw from the study at any time without needing to provide a reason.

Ethical approval for the study was granted by the Ethics Committee of the Faculty of Medicine, University of Kelaniya, Sri Lanka (P/28/05/2022). The trial has also been registered with the Sri Lanka Clinical Trial Registry (SLCTR/2023/003).

Consent

Researchers visit the University Medical Unit to identify the eligible patients. Each patient is given a patient information sheet in their preferred language, and they have the opportunity to clarify doubts with the investigators before providing consent. Informed written consent is obtained prior to enrolment in the study.

Confidentiality

All collected data is anonymised and kept confidential. Questionnaires and laboratory reports are securely stored in locked cabinets, accessible only to the investigators. Personal identification details remain confidential and are not disclosed. Blood samples are securely destroyed after analysis and will not be used for any additional testing. The electronic database will be maintained as a password-protected file.

Termination of the trial

The trial will be terminated if:

- The planned sample size is recruited.
- New information or other evaluations regarding the safety or efficacy of atorvastatin dose that indicate a change in the known risk–benefit profile, such that the risk–benefit is no longer acceptable for subjects participating in the trial.
- Significant violation of good clinical practice (GCP), which compromises the ability to achieve study objectives or compromises subject safety, occurs.

Trial status

The trial commenced in May 2023 according to Protocol Version 2.0, dated August 15, 2022. The first patient was recruited in May 2023. Follow-up is currently ongoing, and to date, 48 patients have been enrolled in the study and their follow-up visits completed.

Protocol amendments

Any protocol amendment will be communicated to all investigators and the ethical review committee of the Faculty of Medicine, University of Kelaniya, Sri Lanka.

Discussion

The prevalence of ACS is rising in South Asia, creating a significant public health challenge. Effective secondary prevention strategies, particularly lipid-lowering therapies, are crucial for reducing recurrent events and enhancing patients' quality of life.

In Sri Lankan clinical practice, a daily nocturnal dose of 40 mg atorvastatin is commonly prescribed for patients with ACS. This preference may stem from clinical observations suggesting adequate LDL-C reduction at this dosage. Importantly, this practice aligns with the National Guidelines for the Management of Dyslipidaemia in Sri Lanka, which recommend initiating atorvastatin at 40 mg or rosuvastatin at 20 mg nocte for secondary prevention in patients without CKD [24]. This contrasts with Western guidelines that often recommend an 80 mg dose of atorvastatin for similar patient populations [25]. However, there is a paucity of local trials supporting the efficacy of this regimen.

While our study primarily focuses on LDL-C levels due to resource constraints, we acknowledge the importance of assessing broader cardiovascular outcomes. Substantial evidence supports the correlation between LDL-C reduction and decreased cardiovascular events.

For instance, a meta-analysis by the Cholesterol Treatment Trialists' Collaboration demonstrated that each 1 mmol/L (approximately 38.7 mg/dL) reduction in LDL-C is associated with a 22% relative reduction in major vascular events [26].

Studies in the Western world have predominantly used atorvastatin 80 mg, which is supported by clinical guidelines as the maximum tolerated dose. A study conducted in Singapore suggested that Asian patients require similar statin doses to achieve target cholesterol levels as their Caucasian counterparts do [8]. However, evidence from India shows varying results.

Agrawal et al. conducted a prospective, randomised, open-label, comparative study involving 240 Indian patients with dyslipidaemia, as defined by the ACC/AHA 2013 lipid guidelines. Participants were randomly assigned to receive either 40 mg or 80 mg of atorvastatin daily, with 120 patients in each group. The follow-up period was 6 months. At the 3-month follow-up, the mean percentage reductions in LDL-C were 47.18 ± 20.81% for the 40 mg group and 50.03 ± 18.06% for the 80 mg group, with no statistically significant difference between the two ($p = 0.118$). The incidence of myalgia was higher in the 80 mg group (7 patients) compared to the 40 mg group (2 patients), which was statistically significant ($p = 0.045$). No significant elevations in CPK levels were observed in either group. This study suggests that in the Indian population with dyslipidaemia, 40 mg of atorvastatin may be as effective as 80 mg in reducing LDL-C levels, with a lower incidence of certain adverse effects. However, it is important to note that the study population did not specifically include patients with ACS, which is the focus of our current research [9].

Most research on lipid-lowering agents has been conducted among Caucasians, with limited data from Asian populations. It is well-established that therapeutic agents can have different effects in South Asians compared to Caucasians [11]. Observations suggest that South Asian patients may achieve similar therapeutic effects with lower doses of statins, potentially due to higher plasma levels of statins in this population [10, 27]. Pharmacokinetic studies have reported higher plasma concentrations of statins in Asians without indicating pharmacokinetic safety issues at equivalent doses [28]. Additionally, Ranasinghe et al. reported that certain minor allele frequencies might increase the risk of statin-induced myotoxicity in Sri Lankans [11].

Given these considerations, it is imperative to conduct localised research to determine the optimal statin dosage that balances efficacy and safety for the Sri Lankan population. While our current study design does not include a biomarker sub-study due to resource limitations, we agree that future research incorporating such analyses would be valuable. We are committed to exploring these avenues as resources and infrastructure permit.

Limitations

Furthermore, our study's single-centre design may limit the generalisability of findings beyond similar tertiary care settings in Sri Lanka. Differences in ethnicity, comorbidity burden, health system structure and prescribing patterns across South Asian countries necessitate caution when extrapolating these results regionally.

Additionally, this study adopts an open-label design due to logistical and resource-related constraints. While we acknowledge that this may introduce potential bias, objective endpoints such as laboratory-based LDL-C measurements were selected to mitigate this effect. Moreover, open-label design facilitates better coordination of care with general practitioners and other specialists, who need to be aware of ongoing statin therapy when managing other concurrent conditions.

Nevertheless, our study serves as an important exploratory effort, laying the foundation for multicentre trials across the South Asian region to establish evidence-based guidelines for statin therapy in diverse populations.

Abbreviations

ACE	Angiotensin converting enzyme
ACS	Acute coronary syndrome
ALT	Alanine transaminase
ARBs	Angiotensin receptor blockers
CABG	Coronary artery bypass grafting
CKD	Chronic kidney disease
BMI	Body mass index
CPK	Creatine phosphokinase
CYP3A4	Cytochrome P4503A4
DM	Diabetes mellitus
GCP	Good clinical practice
HDL-C	High-density lipoprotein cholesterol
LDL-C	Low-density lipoprotein cholesterol
NEQAS	National External Quality Assurance Scheme
NICE	National Institute for Health and Care Excellence
PCI	Percutaneous coronary intervention
SLCTR	Sri Lanka Clinical Trial Registry

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s13063-025-08943-2.

Supplementary Material 1

Supplementary Material 2

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Data sharing statement

All data relevant to the study will be included in the article or uploaded as supplementary information.

Patient and public involvement

The research question for this clinical trial was formulated based on clinical practices observed among Sri Lankan physicians and cardiologists, who prescribe 40 mg of atorvastatin to patients following ACS, noting satisfactory responses. Reports generated from the trial will be accessible to all participants and utilised in their standard management as needed. The study results will be shared with participants and integrated into standard clinical practices.

Authors' contributions

KF contributed to protocol development, and drafted the initial manuscript. NF and CW assisted in patient recruitment planning, clinical trial design, and provided critical review of the protocol. SL contributed to data collection and management. BD supervised the biochemical aspects of the study and contributed to the design of laboratory protocols. SDS and CM provided overall supervision, critically revised the manuscript, and ensured alignment with institutional and ethical standards. All authors reviewed and approved the final version of the protocol.

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Data availability

The study data will be available from the corresponding author upon request.

Declarations

Ethics approval and consent to participate

Ethical approval for the study was obtained from the Ethics Review Committee, Faculty of Medicine, University of Kelaniya (P/28/05/2022). This trial is registered in Sri Lanka Clinical Trial Registry (SLCTR/2023/003). Participation, based on informed consent, is voluntary and participants are free to withdraw from the study without giving any reason and without the withdrawal having any negative impact on the individual.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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