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Original Research

Comparative efficacy and safety of generic rosuvastatin (K-zuva®) versus proprietary rosuvastatin (Crestor®) in patients with hypercholesterolemia: An open-label, 6-week randomized controlled trial

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Abstract

Background: A recent study from Thailand reported that simvastatin is more frequently used than rosuvastatin and that the rate of attaining an optimal low-density lipoprotein-cholesterol (LDL-C) level is low. The rosuvastatin pioneer brand, Crestor®, is costly for many patients in developing countries. Some generic rosuvastatins have become available but there has no evidence from randomized control trials to support the efficacy and safety of generic rosuvastatin formula in Thailand. **Objectives:** To determine whether a generic rosuvastatin (K-zuva®) has a comparative efficacy and safety to branded rosuvastatin (Crestor®). **Methods:** A phase 4, multicenter, randomized, open, active-controlled, parallel-arm study of patients with hypercholesterolemia was conducted to compare the generic rosuvastatin (K-zuva®) to the branded rosuvastatin (Crestor®). The study included a 2-week run-in period and a 6-week treatment period. The primary efficacy endpoint was the mean difference in direct LDL-C levels from baseline to week 6. Safety issues, including treatment-emergent adverse events and clinical laboratory safety parameters, were also studied. Differences between before and after treatment in each group were evaluated using a paired t-test. For comparison between two groups, a two-sample t-test was used. **Results:** Of 107 participants screened, 92 were randomized (46 each in the brand group and generic group). In the brand group, the mean difference in LDL-C was −64.2 mg/dL [95%CI: −77.8 to −50.5], and the mean percent change in LDL-C level was −38.7% [95%CI: −46.0 to −31.3] from baseline to week 6. In the generic group, the mean difference in LDL-C was −69.0 mg/dL [95%CI: −80.0 to −57.9], and the mean percent change in LDL-C was −42.8% [95%CI: −48.5 to −37.0] from baseline to week 6. There was no significant difference in the mean difference (p=0.58) or percentage reduction between the two groups (p=0.37). Incidence of adverse events was similar between the groups. **Conclusions:** K-zuva®, the generic rosuvastatin, had the same efficacy in LDL-C reduction as the branded rosuvastatin, with a similar incidence of adverse effects. Physicians may be reassured to prescribe effective and safe generic rosuvastatin with greater confidence. Our results may promote the use of the less expensive generic rosuvastatin as a substitute for branded rosuvastatin.

Keywords: statin, rosuvastatin, generic drug, hypercholesterolemia

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INTRODUCTION

Cardiovascular disease (CVD) is the leading cause of death in Thailand and worldwide[1]. Dyslipidemia, particularly hypercholesterolemia, is a key factor in the development of CVD. Statins are the most widely used agents for treating hypercholesterolemia. Statin therapy has been associated with significant reductions in cardiovascular morbidity and mortality in patients with established coronary artery disease and in at-risk patients[2,3]. Rosuvastatin, a high-potency statin, has a proven track record of low-density lipoprotein-cholesterol (LDL-C) lowering efficacy and drug safety for over 20 years[4,5]. A multicenter study from Thailand recently reported that simvastatin, a moderate-potency statin, is more frequently used, while the rate of patients attaining an optimal LDL-C level is low[6]. The Thai national list of essential medicines, determined by the Comptroller General's Department for reimbursement, includes simvastatin and atorvastatin, but not rosuvastatin. The rosuvastatin pioneer brand, Crestor®, is considered costly for many patients, as they have to pay for the drug. Although generic rosuvastatin has become available in Thailand at a reduced cost, it is still underused. Physicians may have negative perceptions and attitudes toward generic drugs[7,8]. To increase affordability for most patients, lessen cost concerns, and support rosuvastatin for future Thai national essential medicine lists, it is necessary to prove that generic and proprietary rosuvastatins are equivalent. There has been a lack of high-quality clinical trial evidence supporting the efficacy and safety of generic forms of rosuvastatin in Thailand. K-zuva®, at approximately one-third the price of Crestor®, was registered by the Thai FDA in August 2017 after a bioequivalence study and has become one of the top-two most-used generic rosuvastatin brands in Thailand. Our study objective is to determine whether a generic rosuvastatin (K-zuva®) has a comparative efficacy and safety relative to the brand-name rosuvastatin (Crestor®).

METHODS

Study Design

This was a phase 4, multicenter, randomized, open, active-controlled, parallel-arm study of patients with primary hypercholesterolemia. Patients were screened at four centers located in the central, northern, southern, and northeastern regions of Thailand. The study was conducted in accordance with consensus ethics principles derived from international ethics guidelines, including the Declaration of Helsinki and ICH guidelines for Good Clinical Practice. The participants provided written informed consent prior to enrolment in the study. The protocol and informed consent forms were reviewed and approved by the Central Research Ethics Committee of Thailand (Approval number: CREC067/62BPm). This clinical trial was registered at Thai Clinical Trials Registry: TCTR20221209001.

The first participant was enrolled on March 3, 2020, and the study completion date was Jan 4, 2023. The study included a 2-week stabilization run-in period emphasizing nonpharmacological treatment and a 6-week drug treatment period. The main goal of the stabilization run-in period was to ensure that statin treatment was harmonized. During the 6-week drug treatment period, a stable dose of rosuvastatin was administered. After the stabilization period, the patients who were not adequately controlled were included in the randomized treatment period. The treatment kits were allocated randomly and stratified by site. Patients were randomized 1:1 to receive branded (Crestor®, AstraZeneca) or generic (K-zuva®, Millimed) therapy. The end-of-study visit occurred in week 6. The visit windows were +/−7 days.

Study Population

The inclusion criterion for entering the study was age > 20 years and a diagnosis of primary hypercholesterolemia. The inclusion criterion related to the direct LDL-C thresholds for the run-in period was inadequately controlled hypercholesterolemia based on the sample taken at the screening visit. Inclusion criterion for the randomized period was hypercholesterolemia not adequately controlled[9,10]. The first study protocol used rosuvastatin 10 mg daily in statin-naive subjects. Owing to slow recruitment during the SARS-CoV-2 pandemic, the protocol was amended to include those whose LDL-C levels were not adequately controlled despite taking other statins. They were required to discontinue the medications for at least two weeks during the run-in period to be eligible. A dosage of either 10 or 20 mg was used, and dose selection was applied in stratified randomization between the K-zuva® and Crestor® allocation arms. The exclusion criteria were: homozygous familial hypercholesterolemia; acute coronary syndrome, percutaneous coronary intervention, coronary artery bypass graft surgery, stroke, or surgical intervention for peripheral vascular disease within the previous three months; presence of any clinically significant uncontrolled endocrine disease known to influence serum lipids or lipoproteins; uncontrolled hypertension (systolic blood pressure > 160 mmHg or diastolic blood pressure > 100 mmHg; creatinine phosphokinase > 2 times of the upper limit of normal; transaminase enzyme > 2 times of the upper limit of normal; serum creatinine > 2.0 mg/dL; history of statin-induced myopathy or rhabdomyolysis; known history of hypersensitivity reaction to statins; and breast-feeding or childbearing-potential women with inadequate contraception.

Study Outcomes

The primary efficacy endpoint was the mean difference in direct LDL-C levels from baseline to week 6. The secondary efficacy endpoints included the percent change in direct LDL-C from baseline to week 6, and the mean difference and percent change in total cholesterol (TC), high-density lipoprotein cholesterol (HDL-C), and triglyceride (TG) levels from baseline to week 6. Safety assessments included treatment-emergent adverse events, clinical laboratory safety parameters, vital signs, and physical examination.

Statistical Analysis

For primary efficacy analysis, the non-inferiority margin for the LDL-C difference was set at 10 mg/dL. If there was truly no difference between the generic and branded treatment, then

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41 patients for each group were required to be 80% sure that the lower limit of a one-sided 95% confidence interval would be above the non-inferiority limit of −10. In anticipation of a 10% dropout rate, at least 90 patients were included in the study. The randomized population included all participants who signed their informed consent and were allocated to a randomized treatment arm on an intent-to-treat basis. The primary efficacy analysis population was the modified intention to treat population, defined as all participants in the randomized population with an evaluable primary efficacy endpoint. The primary efficacy endpoint was considered evaluable when both the baseline and week 6 direct LDL-C values were available. Safety was analyzed according to the treatment received.

Continuous data for each treatment group were summarized descriptively. Categorical and ordinal data were summarized using the number and percentage of participants in each treatment group. Participants with missing data were not counted in the percentages and were not displayed. Differences between before and after treatment in each group were evaluated using a paired t-test. For comparison between two groups, a two-sample t-test was used, and the difference was considered statistically significant when the p-value was < 0.05 (two-sided).

RESULTS

Overall, 107 participants were screened, 15 (14%) of whom were considered screen failure. Therefore, 92 participants were enrolled in the run-in period and randomized (46 each in the brand group and generic group). The number of participants who discontinued the intervention was not statistically lower in the generic group (one participant [2.1%]) than in the brand group (two participants [4.4%]). The reason for treatment discontinuation was the occurrence of adverse events (AEs). The efficacy endpoint for Crestor® was evaluable in 39 and 5 subjects who received 10 mg and 20 mg, respectively. For K-zuva®, it was evaluable in 41 and 4 subjects who received 10 mg and 20 mg, respectively.

The baseline demographic and disease characteristics were generally well balanced between the treatment groups (Table 1). In the brand group, the mean age was 64.4 years (range 44–87 years) and the proportion of females was 56.5%. The mean BMI at baseline was 25.7 kg/m^2, and seven participants (15.2%) had a BMI > 30 kg/m^2. In the generic group, the mean age was 67.3 years (range 43–88 years), and the proportion of females was 73.9%. The mean BMI at baseline was 25.6 kg/m^2, and 6 participants (13.1%) had a BMI higher than 30 kg/m^2. The risks of CVD-related health conditions in the brand group included hypertension (65.2%), diabetes mellitus (32.6%), and prior cardiovascular disease (13.0%). The most common CVD-related health conditions in the generic-drug group were hypertension (60.9%), diabetes mellitus (23.9%), and prior CVD (15.2%). Since baseline LDL-C was not different between treatment arms in either the 10 or 20 mg groups, and there were small numbers of subjects who used rosuvastatin 20 mg, data from different doses were summed and compared, as shown in Table 2. The subgroup analysis of 10 mg rosuvastatin is provided in Supplementary Table I.

In the brand group, the mean difference in LDL-C was −64.2 mg/dL [95%CI: −77.8 to −50.5], and the mean percent change in LDL-C level was −38.7% [95%CI: −46.0 to −31.3] from baseline to week 6. In the generic group, the mean difference in LDL-C was −69.0 mg/dL [95%CI: −80.0 to −57.9] and the mean percent

Table 1. Baseline patient characteristics.

	Brand group (N=46)	Generic group (N=46)	p value
Female, n (%)	26 (56.5)	34 (73.9)	0.08
Age (years), mean (SD)	64.4 (8.8)	67.3 (10.0)	0.14
Weight (kg), mean (SD)	65.8 (12.7)	63.7 (11.2)	0.41
BMI (kg/m^2), mean (SD)	25.7 (4.5)	25.6 (4.2)	0.94
BMI category, n (%)			
<25	23(50.0)	22 (47.8)	
25–30	16(34.8)	18 (39.1)	
30–35	6(13.0)	4 (8.7)	
>35	1(2.2)	2 (4.4)	0.83
Prior use of other statins, n (%)	29(63.0)	30 (65.2)	0.82
Medical history, n (%)			
Hypertension	30 (65.2)	28 (60.9)	0.66
Diabetes mellitus	15 (32.6)	11 (23.9)	0.35
Prior cardiovascular disease	6 (13.0)	7 (15.2)	0.76

Table 2. Lipid profile change from baseline to week 6 (modified intention to treat population).

	Brand group* Mean(SD)	Generic group** Mean(SD)	p value
LDL-C (mg/dL)			
At baseline	149.3 (38.6)	153.7 (30.0)	0.55
At week 6	85.0 (21.2)	86.0 (23.7)	0.84
Difference	−64.2 (44.8)	−69.0 (36.7)	0.58
Cholesterol (mg/dL)			
At baseline	217.3 (37.2)	222.9 (35.9)	0.46
At week 6	157.6 (31.8)	158.0 (34.7)	0.96
Difference	−60.2 (43.8)	−66.5(39.6)	0.48
HDL-C (mg/dL)			
At baseline	53.0 (12.2)	56.1(20.3)	0.36
At week 6	56.4 (14.4)	55.6(17.0)	0.81
Difference	2.9 (8.1)	−0.69 (15.2)	0.16
Triglyceride (mg/dL)			
At baseline	127.1 (61.2)	117.0 (37.8)	0.34
At week 6	110.2 (64.6)	99.7 (36.2)	0.34
Difference	−16.3 (49.2)	−17.4 (30.8)	0.89

*N at baseline = 46, N at week 6 =44, **N at baseline = 46, N at week 6 =45

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change in LDL-C was −42.8% [95%CI: −48.5 to −37.0] from baseline to week 6. There was no significant difference in the mean difference (p=0.58) or percentage reduction (p=0.37) in LDL-C between the two groups. In the brand group, the mean difference in TC was −60.2 mg/dL [95%CI: −73.5 to −46.9] and the mean percent change in TC was −26.0% [95%CI: −31.6 to −20.5] from baseline to week 6. In the generic group, the mean difference in TC was −66.5 mg/dL [95%CI: −78.4 to −54.6] and the mean percent change in TC was −28.9% [95%CI: −33.5 to −24.2] from baseline to week 6. There was no significant difference in the mean difference or percentage reduction in TC between the two groups. We found no significant change in the mean differences or mean percent changes in HDL-C and TG levels from baseline to week 6 (Table 2).

No significant difference in body weight was found between baseline and week 6 [64.6 kg (SD=12.0) and 64.4 kg (SD=12.0) respectively, p = 0.13]. There was no significant difference in body weight change between the two groups (p=0.65).

As a result of analyzing the incidence of total AEs (Table 3), the brand group showed 15 cases in 32.6% (15/46) of patients and the generic name group showed 14 cases in 30.4% (14/46) of patients. With regard to myalgia, the brand group showed 5 cases in 10.9% (5/46 patients), and the generic name group showed 7 cases in 15.2% (7/46 patients). For the AEs that caused clinical trial discontinuation, two cases of drug-related "myalgia and headache" occurred in the brand group, and one case of "heart failure" occurred in the generic group, which was considered a nondrug-related AE. There were no significant differences in the incidence of drug-related AEs, myalgia, or AEs that caused clinical trial discontinuation between the brand and generic groups. No significant changes from baseline or differences between groups were observed in the mean CPK, AST, and ALT levels during the short-term 6-week follow-up period. No patient in the brand or generic rosuvastatin groups showed an increase in CPK, AST, or ALT levels by more than three times the upper limit of normal (Figure 1).

Table 3. Safety assessment at week 6.

	Brand group (N=46)	Generic group (N=46)	p value
Total AEs, n(%)	15 (32.6)	14 (30.4)	0.82
Myalgia, n(%)	5 (10.9)	7 (15.2)	0.53
AEs leading to discontinuation, n(%)	2 (4.3)	1 (2.2)	0.55
CPK (IU/L) at week 6, mean (SD)	132.2 (68.2)	126.8 (61.3)	0.69
ALT (IU/L) at week 6, mean (SD)	28.7 (12.9)	29.5 (16.9)	0.81
AST (IU/L) at week 6, mean (SD)	25.2 (6.4)	28.2 (9.1)	0.08

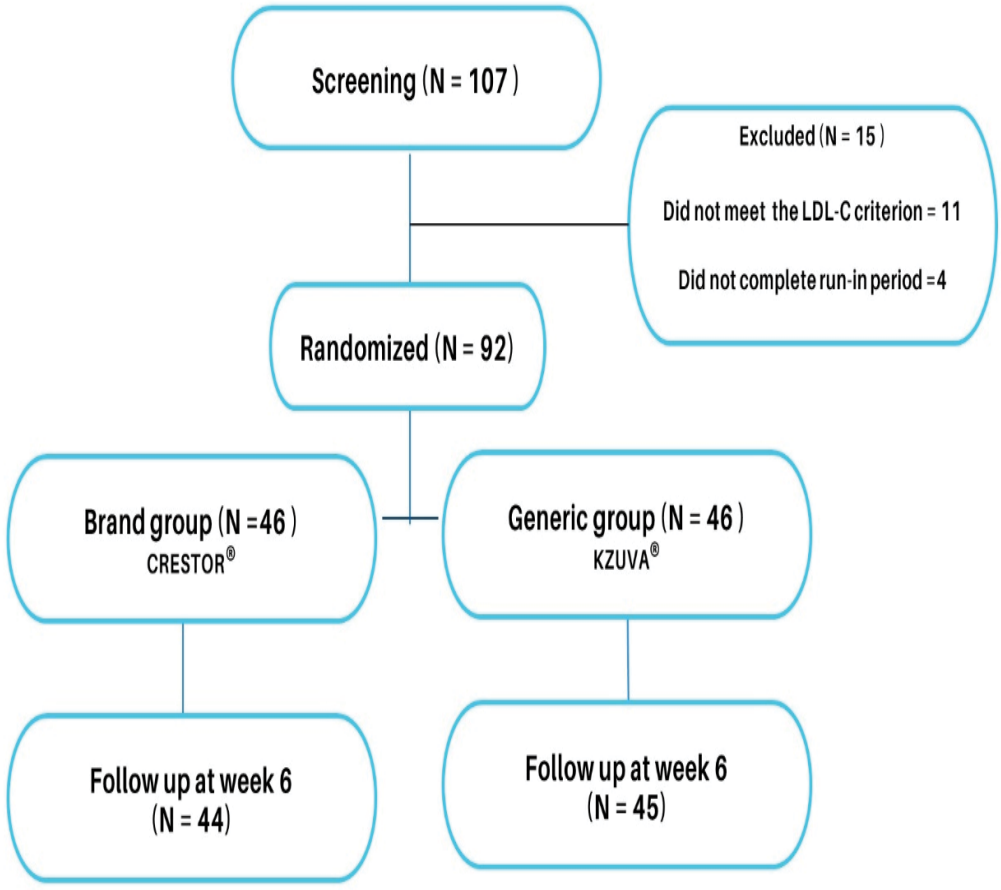

Figure 1. Study flowchart

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DISCUSSION

The present study showed that the generic rosuvastatin (K-zuva®) produced by Millimed in Thailand has therapeutic equivalence with branded rosuvastatin. LDL-C reduction with K-zuva was not inferior to that of the proprietary rosuvastatin (Crestor). The safety profiles of the two formulations did not differ. Our study is the first RCT conducted in Thailand to compare generic and proprietary rosuvastatin. To comply with the 2019 ESC/EAS dyslipidemia management guidelines, we assessed the response to therapy six weeks after drug initiation and found that generic and branded rosuvastatin treatments had similar mean differences in LDL-C levels. Some studies have suggested that the response to statins, particularly low-dose rosuvastatin, may be exaggerated in Asians as compared to that in Westerners[11,12]. The percent reduction in LDL-C in the generic and brand rosuvastatin groups was 42.8% and 38.7%, respectively, which seemed close to the expected value. These results were in line with those of Korean and Indian studies and were consistent with the expectations of the meta-analysis[13–15].

With respect to the safety profile, generic rosuvastatin treatment was well tolerated and showed a similar incidence of total AEs as the branded rosuvastatin treatment. AEs leading to discontinuation were very rare and did not differ between the two groups. Previous studies have reported that drug discontinuation due to AEs occurred in 2.9–4.1% of patients receiving 10 mg rosuvastatin[16,17]. In the current study, the rate of AEs leading to discontinuation in the generic drug group was 2.2%, similar to that in the brand group (4.3 %). Therefore, our study demonstrated that generic rosuvastatin is as effective as a branded lipid-lowering agent in patients with primary hypercholesterolemia, without safety concerns.

Although the efficacy and safety of rosuvastatin have been proven, it is not included in the Thai national list of essential medicines. In the era of cost-effective strategies, high-cost drugs pose a significant financial burden on the healthcare system. When effective and safe generic rosuvastatin becomes available, cost concerns may be alleviated. In addition, after acknowledging the study results, physicians may be reassured to prescribe generic rosuvastatin with greater confidence. Our results should promote the use of the less expensive generic rosuvastatin as a substitute for branded rosuvastatin when needed.

Limitations

Although the baseline characteristics and blood lipid panels were comparable between the treatment groups owing to the randomization process, open-label treatment may result in different lifestyle changes between the two treatment arms. We recommended the same advice to all patients during the run-in period and before randomization. Following the same advice during pre-drug period and after six weeks of statin treatment, there was no difference in body weight change between the groups. In addition, lifestyle modifications have a drastically lower impact on LDL-C than high-potency statins. Our study had a very small number of patients who received the 20 mg formula, and most results stemmed from the 10 mg treatment. Therapeutic equivalence was applied with hard evidence for the 10 mg but not for the 20 mg preparation.

CONCLUSIONS

K-zuva®, the generic rosuvastatin, had the same efficacy in LDL-C reduction as the branded rosuvastatin, with a similar incidence of adverse effects. Our study provides a reassurance and should promote substituting this less expensive generic drug either for branded rosuvastatin or for low to moderate-potency statins. With reduced drug cost and a higher rate of attaining an optimal LDL-C level, we anticipate the improvement in both health economics and health outcomes.

AUTHOR CONTRIBUTIONS

All authors contributed to conceptualization of the study, developed methodology, and took part in conducting the research. Supervision and funding acquisition were provided by SP and SS. SP and SS also performed the statistical analysis and made significant contributions to the initial draft. All authors critically reviewed and edited the paper, approved the final manuscript, and agreed to take responsibility for the content of the manuscript.

CONFLICT OF INTEREST

The authors declare no financial or non-financial conflicts of interest related to the publication of this manuscript. Millimed, Thailand, was not involved in the trial design or study. The authors independently designed and conducted this study. Data analysis and interpretation were performed by the authors, who also prepared and submitted the manuscript for publication.

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Supplementary Table I. Lipid profile change in 10 mg rosuvastatin receivers, from baseline to week 6 (mITT population)

	Brand group*	**Generic group****	**P value**
	Mean(SD)	**Mean(SD)**	
LDL-C (mg/dL)			
At baseline	150.7(38.0)	157.2(28.2)	0.384
At week 6	84.3(21.5)	83.9(20.6)	0.936
Difference	66.4(45.4)	73.3(35.0)	0.447

*N=39, ** N=41

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