Research Square

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Investigating the synergistic effects of Telmisartan and Amlodipine with Metformin in patients with metabolic syndrome

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Abstract

Purpose

This study aimed to evaluate the synergistic therapeutic effects of telmisartan and amlodipine when combined with metformin in the management of metabolic syndrome. The study assessed their impact on blood pressure, glycaemic control, and lipid profile, with emphasis on improving cardiovascular and metabolic outcomes beyond their primary pharmacological effects.

Methodology:

A six-month prospective, open-label comparative study was conducted at the Government General Hospital in Ananthapuramu. A total of 136 patients with metabolic syndrome were randomly assigned to two groups: telmisartan plus metformin (n = 68) and amlodipine plus metformin (n = 68). Blood pressure, random blood sugar, HbA1c, and total cholesterol levels were assessed at baseline and after 24 weeks. Data were analysed using statistical tests, with p-values < 0.05 considered significant.

Results

Both treatment groups demonstrated significant improvements in blood pressure and metabolic parameters over 24 weeks. The telmisartan plus metformin group showed greater reductions in diastolic blood pressure, glycaemic indices, and total cholesterol levels, indicating superior metabolic benefits. Overall, telmisartan was associated with broader cardiometabolic benefits, but amlodipine had greater systolic blood pressure-lowering effects.

Conclusion

Telmisartan combined with Metformin showed superior improvement in DBP, insulin resistance & Cholesterol levels, while Amlodipine was more effective in reducing SBP. Study limitations warrant further research to establish optimal dosing and broader benefits.

Introduction

Metabolic syndrome (Met S) is a group of health problems that tend to occur together high blood pressure, increased waist size, high blood sugar, high triglycerides and low HDL cholesterol. When these conditions appear in the same person, the chances of developing type 2 diabetes and heart disease increase sharply [1]. In India, Met S has become a growing public-health concern due to changes in lifestyle, reduced physical activity, and rising rates of obesity. A large systematic review showed that almost 30% of Indian adults may have Met S, which means nearly one in every three adults is at risk [2].

In Andhra Pradesh (AP), this concern is equally important. A community-based study conducted in urban elderly people from Tirupati, Chittoor district, found that 34.6% of older adults met the criteria for metabolic syndrome [3]. This means that one out of every three elderly persons in this region may silently carry multiple risk factors for serious diseases. Beyond statistics, the condition affects the daily lives of people many deal with long-term tiredness, stress from multiple medications, and the worry of developing diabetes or heart problems. Families, especially in semi-urban and rural AP, often struggle with limited access to preventive care and the added financial burden of chronic illnesses.

High blood pressure and insulin resistance are two major components of Met S. They commonly appear together and worsen each other. Many patients require more than one medicine to control their blood pressure and blood sugar. For hypertension, doctors often prescribe a combination of medicines such as an angiotensin receptor blocker (ARB) and a calcium-channel blocker (CCB). For insulin resistance and high blood sugar, metformin remains the first and most reliable choice.

Among ARBs, telmisartan is unique because, in addition to lowering blood pressure, it has a mild “PPAR-γ activation” effect a mechanism also used by some insulin-sensitizing drugs. This property may help improve insulin resistance. Scientific studies and meta-analyses have shown that telmisartan can reduce fasting glucose, insulin levels and HOMA-IR better than several other ARBs [4–5]. In experimental studies, telmisartan also improved lipid levels and insulin sensitivity in animals fed a high-fat diet [6].

Amlodipine, a commonly used CCB, is effective for blood-pressure control and is often combined with ARBs for better cardiovascular protection. While amlodipine alone does not directly improve insulin resistance, it works well with Metformin to protect blood vessels and reduce long-term complications.

Metformin, the cornerstone treatment for insulin resistance and early diabetes, reduces the liver’s glucose production and improves how the body uses insulin. Together, these three medicines telmisartan, amlodipine and metformin cover the major components of Met S: blood pressure, insulin resistance, and glucose control.

However, a major gap remains in current research, numerous studies have evaluated telmisartan against other ARBs, and there remains limited research on the combination effects of telmisartan with metformin and amlodipine with metformin being used together in patients specifically diagnosed with metabolic syndrome. Another gap is the lack of data from Indian populations, especially from Andhra Pradesh, where the burden of Met S is high but research on combined therapeutic approaches is scarce. Also, while telmisartan has shown metabolic benefits in many studies, some trials reported inconsistent results, suggesting that more research is needed to understand which patient groups benefit the most [7].

Therefore, the novelty of this study lies in evaluating the synergistic effect of telmisartan, amlodipine and metformin together in patients with metabolic syndrome. This triple-drug approach aims to address multiple pathways of the disease simultaneously something not well explored in existing literature.

Conducting this study in Andhra Pradesh adds regional relevance and may help clinicians make better treatment decisions for patients in this population.

Metabolic syndrome is a growing challenge in Andhra Pradesh and India as a whole. With increasing rates of hypertension, insulin resistance and obesity, there is an urgent need for comprehensive and practical treatment strategies. This research aims to fill an important evidence gap by studying whether a combination of telmisartan, amlodipine and metformin can provide added benefits for patients living with metabolic syndrome.

Materials and Methods

Study Design and Setting

This study was designed as a prospective, randomized, open-label, parallel-group comparative clinical study. It was conducted in the Department of General Medicine at the Government General Hospital, Ananthapuramu, Andhra Pradesh, India. The study period extended over six months, from November 2024 to May 2025.

Study Population

Inclusion Criteria

Patients eligible for the study were those aged between 30 and 85 years. They had to meet the Harmonized Criteria for Metabolic Syndrome, which involves having at least three of the following conditions: increased waist circumference, elevated blood pressure, elevated triglycerides, reduced HDL cholesterol, or elevated blood glucose. Additionally, participants needed to be hypertensive and diabetic, require combination therapy of ARB (Angiotensin Receptor Blocker) + Metformin, CCB (Calcium Channel Blocker) + Metformin. Finally, all participants were required to provide written informed consent before being included in the study.

Exclusion Criteria

Patients were excluded from the study if they had a history of type 1 diabetes or uncontrolled type 2 diabetes, defined by an HbA1c level greater than 10%. Other exclusion criteria included significant hepatic impairment, pregnancy, or lactation. Participants with hypersensitivity to any of the study medications; telmisartan, amlodipine, or metformin, were also excluded. Additionally, individuals currently using other glucose-lowering medications besides metformin & those who were using lipid lowering agents were also excluded.

Intervention Details

- Telmisartan (Group-A): 40 mg once daily, titrated up to 80 mg if blood pressure remained uncontrolled.
- Amlodipine (Group-B): 5 mg once daily, increased to 10 mg based on clinical response.
- Metformin: 500 mg twice daily initially, titrated up to 1000 mg twice daily depending on tolerance.

Dose adjustments followed standard clinical practice guidelines.

Sample Size

The sample size for the study conducted by Vaibhav Watts, Bhupinder Singh, et al., was calculated based on the expected differences in mean systolic blood pressure (SBP) and HbA1c between the treatment groups. The calculation assumed 80% power, a two-sided alpha of 0.05, and a mean detectable difference of 5 mmHg in SBP and 0.3% in HbA1c. Standard deviations were derived from data in previous clinical studies. Based on these assumptions, a minimum of 56 participants per group was required. To account for a 20% dropout rate, the final target sample size was set at 136 participants (Fig. 1).

Flow diagram showing enrolment, follow-up, exclusions, and final analysis of participants in Group A (telmisartan + metformin) and Group B (amlodipine + metformin). Final analysed sample: n = 136.

Study Procedure

Baseline Evaluation

After obtaining consent, baseline demographic and clinical data were collected. Anthropometric parameters (weight, BMI, waist circumference) and vital signs were recorded at baseline. Blood pressure was measured using a calibrated digital sphygmomanometer after 5 minutes of rest.

Laboratory Investigations

Since fasting samples were not collected, metabolic evaluation was based on; Random Blood Sugar (RBS), HbA1c, Total cholesterol.

Blood samples were collected at; Baseline (0 weeks) & End of Visits study (24 weeks).

Follow-Up

Participants were assessed every two months throughout the study. Each assessment included measurements of systolic and diastolic blood pressure (SBP and DBP), evaluation of medication adherence, and monitoring for any side effects or adverse drug reactions. Additionally, any interim clinical changes were documented, and safety labs, including tests for renal and hepatic function, were repeated if clinically indicated. These bi-monthly assessments were designed to ensure participant safety and evaluate the effectiveness of the treatment regimen.

Final Evaluation (24 weeks)

All baseline measurements (BP, RBS, HbA1c, Total cholesterol) were reassessed.

Outcome Measures

The study's primary outcomes are changes in systolic and diastolic blood pressure (SBP) from baseline to final visit. The secondary objectives include the change in random blood sugar (RBS), glycated haemoglobin (HbA1c), and total cholesterol from baseline to the final visit, as well as the proportion of patients achieving the target blood pressure of less than 130/80 mmHg at the final visit.

Data Collection and Management

Study data were recorded in pre-designed case report forms (CRFs). Two investigators independently verified all entries for accuracy. Data were anonymized and stored securely with restricted access. Only coded identifiers were used for analysis.

Statistical Analysis

Statistical analysis was conducted using IBM SPSS Statistics version 26.0. Continuous variables were expressed as mean ± standard deviation (SD), while categorical variables were reported as numbers and percentages. Within-group comparisons for parameters such as SBP, DBP, RBS, HbA1c, and total cholesterol were performed using the paired t-test, whereas between-group differences were assessed using the independent t-test. Categorical outcomes were analyzed using the chi-square test. A p-value of less than 0.05 was considered statistically significant. All statistical evaluations adhered to the intention-to-treat (ITT) principle.

Results

Table 1
Baseline Demographic and Clinical Characteristics of Study Participants

Variables	Group A: Telmisartan + Metformin (n = 68)	Group B: Amlodipine + Metformin (n = 68)	p-value
Age (years), mean ± SD	60.9 ± 10.4	62 ± 10	0.5038
Male (n%)	44.1%	55.9%	0.6012
Female (n%)	38.2%	61.8%	
BMI (kg/m^2), mean ± SD	25.6 ± 4.8	24.7 ± 3.6	0.1896
Waist circumference (cm), mean ± SD	76.8 ± 9.5	77 ± 10.6	0.9325
Duration of hypertension (years), mean ± SD	5.4 ± 3.7	5.8 ± 4.5	0.6241
Duration of T_2DM (years), mean ± SD	5 ± 4.1	7.3 ± 5	0.0046

Baseline demographic and clinical characteristics of the study population Data are presented as mean ± SD or n (%). $p < 0.05$ was considered statistically significant.

Table 1 outlines the study population's baseline demographics and clinical features. A total of 136 individuals were included, with 68 in Group A (Telmisartan + Metformin) and Group B (Amlodipine + Metformin). The two groups were comparable in terms of age, gender distribution, body mass index, waist circumference, and duration of hypertension ($p > 0.05$). However, the duration of type 2 diabetes mellitus in Group B was considerably longer than in Group A ($p = 0.0046$).

Table 2
Comparison of Clinical Parameters during Visit-1

Parameters	Group A: Telmisartan + Metformin (n = 68)	Group B: Amlodipine + Metformin (n = 68)	p-value
SBP (mmHg), mean ± SD	147 ± 10	161 ± 14	< 0.0001
DBP (mmHg), mean ± SD	90 ± 5	89 ± 4	0.5447
Random Blood Sugar (mg/dl), mean ± SD	160 ± 26.5	188 ± 30.2	< 0.0001
HbA1c (%), mean ± SD	5.7 ± 1.1	8.5 ± 2.4	< 0.0001
Total Cholesterol (mg/dl), mean ± SD	181.4 ± 23.7	192.1 ± 35.5	0.0415

Baseline comparison of blood pressure and metabolic parameters between treatment groups Data are presented as mean ± SD. $p < 0.05$ was considered statistically significant.

Table 2 compares the two groups clinical data from the first visit. Group B showed significantly higher systolic blood pressure, random blood sugar, HbA1c, and total cholesterol levels than Group A ($p < 0.05$). Diastolic blood pressure was not significantly different between groups ($p > 0.05$).

Table 3
Comparison of Blood Pressure Changes Between Groups

Parameter	Group-A First Visit	Group-A Final Visit	Mean Change	Group-B First Visit	Group-B Final Visit	Mean Change	p-value (between groups)
SBP (mmHg)	147 ± 10	132 ± 12	15 mmHg	162 ± 14	143 ± 18	19 mmHg	< 0.0001
DBP (mmHg)	90 ± 5	80 ± 9	10 mmHg	90 ± 4	82 ± 8	8 mmHg	< 0.0001

Changes in systolic and diastolic blood pressure from baseline to 24 weeks Data are presented as mean ± SD. $p < 0.05$ was considered statistically significant.

Table 3 shows changes in systolic and diastolic blood pressure from the first visit to the final visit in both groups. Group A demonstrated a reduction in systolic blood pressure from 147 ± 10 mmHg to 132 ± 12 mmHg (mean reduction: 15 mmHg), while Group B showed a reduction from 162 ± 14 mmHg to 143 ± 18 mmHg (mean reduction: 19 mmHg). Diastolic blood pressure decreased by 10 mmHg in Group A and by 8 mmHg in Group B. The intergroup differences in blood pressure reduction were statistically significant ($p < 0.0001$).

Table 4
Comparison of Glycaemic Parameters Between Groups

Parameter	Group-A First Visit	Group-A Final Visit	Mean Change	Group-B First Visit	Group-B Final Visit	Mean Change	p-value (between groups)
RBS (mg/dl)	160 ± 26	138 ± 25	22 mg/dl	188 ± 30	172 ± 33	16 mg/dl	< 0.0001
HbA1c (%)	5.6 ± 1.1	5.1 ± 1.1	0.5%	8.5 ± 2.3	8 ± 2	0.5%	< 0.0001

Changes in glycaemic parameters from baseline to 24 weeks Data are presented as mean ± SD. $p < 0.05$ was considered statistically significant.

The mean RBS in Group A decreased from 160 ± 26 mg/dl at baseline to 138 ± 25 mg/dl after 24 weeks, while Group B decreased from 188 ± 30 mg/dl to 172 ± 33 mg/dl. HbA1c levels fell from 5.6 ± 1.1% to 5.1 ± 1.1% in Group A and from 8.5 ± 2.3% to 8.0 ± 2.0% in Group B. Group A demonstrated much better glycemic control than Group B ($p < 0.0001$).

Table 5
Comparison of Lipid Parameter between Groups (Total Cholesterol)

Parameter	Group-A First Visit	Group-A Final Visit	Mean Change	Group-B First Visit	Group-B Final Visit	Mean Change	p-value (between groups)
Total Cholesterol (mg/dl)	181 ± 24	167 ± 25	14 mg/dl	192 ± 36	183 ± 34	9 mg/dl	< 0.0001

Changes in total cholesterol levels during the study period Data are presented as mean ± SD. $p < 0.05$ was considered statistically significant.

Table 5 shows variations in total cholesterol levels from baseline to 24 weeks. Group A showed a greater reduction in total cholesterol (14 mg/dl) than Group B (9 mg/dl). There was a statistically significant

difference in cholesterol decrease between the two groups ($p < 0.0001$).

Table 6
Blood Pressure Control at 24 Weeks

BP Control Status (< 130/80 mm Hg)	Group-A (n = 68)	Group-B (n = 68)	p-value
Achieved BP Control, n (%)	47% (32)	34% (23)	0.1619
Not Achieved, n (%)	53% (36)	66.2% (45)	

Blood pressure control status (< 130/80 mmHg) at 24 weeks Data are presented as n (%). $p < 0.05$ was considered statistically significant.

Table 6 shows the proportion of patients who achieved blood pressure management (< 130/80 mmHg) at 24 weeks. Group A had a higher percentage of patients who achieved their goal blood pressure than Group B (47% vs 34%). However, there was no statistically significant difference between the two groups ($p = 0.1619$).

Discussion

This study compared the effects of telmisartan plus metformin with amlodipine plus metformin in individuals with metabolic syndrome, focusing on blood pressure control, glycaemic indices, and lipid profile during a 24-week period. The results show that although both regimens were successful in improving cardiometabolic parameters, amlodipine plus metformin resulted in a relatively larger reduction in systolic blood pressure, while telmisartan plus metformin provided superior benefits on glycaemic control and lipid reduction.

Comparison of Blood Pressure Outcomes

The current study found that both treatment groups had significant reductions in systolic and diastolic blood pressure from baseline to the last visit, demonstrating the antihypertensive efficacy of both regimens. The amlodipine plus metformin group showed a numerically greater reduction in systolic blood pressure, whereas the telmisartan plus metformin group demonstrated a relatively greater reduction in diastolic blood pressure (Table 3). This pattern is consistent with the known pharmacodynamic characteristics of calcium channel blockers and angiotensin receptor blockers. Watts et al.[8] found that telmisartan, like ramipril, induced a significant and sustained drop in both systolic and diastolic blood pressure in hypertensive patients with insulin resistance.

Telmisartan's efficacy as an antihypertensive medication is supported by the extension of blood pressure reduction shown in our investigation, which is in line with their findings. Unlike Watts et al.'s study[8], which compared two renin-angiotensin system blockers, our study compares telmisartan (angiotensin receptor blocker) to amlodipine (calcium channel blocker), demonstrating that amlodipine has a stronger effect

on systolic blood pressure, telmisartan provides a more balanced blood pressure control profile. Although a higher proportion of patients in the telmisartan group achieved the target blood pressure (< 130/80 mmHg), the difference between groups was not statistically significant. This conclusion is consistent with the findings of Watts et al., [8] who found that telmisartan efficiently controlled blood pressure with superiority over ramipril, implying that telmisartan's advantage may extend beyond blood pressure lowering alone.

The results align closely with the study by Tripathi et al. (2016)[10], who reported that amlodipine was highly effective in lowering systolic blood pressure but had minimal favourable effects on metabolic parameters. Similarly, Negro and Hassan (2006)[11] demonstrated that both telmisartan and amlodipine effectively reduce blood pressure in hypertensive diabetic patients, with no major differences in overall antihypertensive efficacy.

Glycaemic Control and Insulin Resistance

The present study's primary finding is that the telmisartan plus metformin group improved glycaemic indices much more than the amlodipine plus metformin group. A key finding of this study was the significantly greater improvement in glycaemic parameters observed in the telmisartan plus metformin group. Group A had a greater reduction in random blood sugar and HbA1c levels than Group B, while receiving the same metformin (oral hypoglycaemic) medication (Table 4). This suggests an additional glucose-lowering effect attributable to telmisartan. These results are consistent with Watts et al. (2019)[8], who found that telmisartan strongly improved insulin resistance and glycaemic indices in hypertensive individuals compared to ramipril. The authors attribute this beneficial effect to telmisartan's partial PPAR-γ agonistic action, which improves insulin sensitivity. This study extends on previous findings by demonstrating that telmisartan continues to provide metabolic advantages even when combined with metformin, emphasizing its use in individuals with metabolic syndrome.

Lipid Profile Improvement

Total cholesterol levels lowered considerably in both groups (Table 5); however, the decrease was substantially greater in the telmisartan plus metformin group. Previous research has shown that telmisartan improves lipid metabolism by modulating adipocyte differentiation and fatty acid metabolism via PPAR-γ activation. The findings correlate with the results reported by Negro and Hassan (2006)[11], who found that telmisartan improved lipid markers but not amlodipine in hypertensive patients with type 2 diabetes. Furthermore, Dhondge et al.'s (2024)[9] larger pathophysiological insights underline the importance of concurrently treating insulin resistance and dyslipidaemia in lowering long-term cardiovascular risk in metabolic syndrome. Our research findings support this concept by demonstrating that telmisartan offers metabolic benefits that extend beyond blood pressure control.

Clinical Implications in Metabolic Syndrome

Metabolic syndrome is a complex phenomenon that include hypertension, insulin resistance, and dyslipidaemia. According to Dhondge et al. (2024)[9], treating only one component of the syndrome is

insufficient to minimize cardiovascular morbidity and progression to type 2 diabetes. The current study shows that telmisartan combined with metformin has a greater overall cardiometabolic benefit than amlodipine combined with metformin, making it a better treatment option in this high-risk population.

Limitations

Limitation of our study is the inability to determine the optimal doses of Telmisartan and Amlodipine for the management of metabolic syndrome. This is because our study design did not include administering all possible doses of Telmisartan (20mg, 40 mg and 80 mg) and Amlodipine (2.5mg, 5 mg and 10 mg) to each participant. Lack of randomization may introduce selection bias and confounding factors.

Conclusion

Although both drugs showed significant results, Telmisartan was consistently more effective and superior to Amlodipine when used along with Metformin in controlling the diastolic blood pressure, improving insulin resistance and reducing cholesterol levels at the end of 6th month (Final visit). Amlodipine slightly affects cholesterol and blood sugar levels but has a strong positive effect on lowering systolic blood pressure when used with Metformin. Though this study had few limitations with respect to randomization and determining the optimal dose of Telmisartan and Amlodipine for managing metabolic syndrome. Further studies can be done to look for the various beneficial effects of both Telmisartan and Amlodipine.

Declarations

Ethics approval

The Institutional Ethics Committee (IEC), Balaji College of Pharmacy- Government General Hospital, Ananthapuramu, approved the study. Written informed consent was obtained from all participants before enrolment. The study adhered to the Declaration of Helsinki and Good Clinical Practice (GCP) guidelines.

Consent to participate

All participants provided written informed consent at enrolment and the protocol was conducted following the principles of the Declaration of Helsinki.

Consent for publication:

Patients signed informed consent regarding publishing their anonymized data.

Competing interests

The authors declare no competing interests.

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No funding was received for conducting this study.

Author Contribution

All authors contributed substantially to this work. Vaishnavi Savadi: conceptualization, data curation, methodology, formal analysis, writing-original draft. Thasleema Nusrath Shaik: conceptualization, investigation, data curation, formal analysis. Usha Boya: conceptualization, data curation, investigation, writing original draft. Suveshna Dasari: conceptualization, data curation, investigation, writing original draft. Mohammed Asif Mulla: project administration, conceptualization, formal analysis, supervision. Rajavardhana Thamineni: statistical visualization, writing review & editing, collected and verified the data, supervision. All authors reviewed final manuscript.

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Data Availability

Data is available upon reasonable request.

Code Availability

Available upon reasonable request.

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Figures

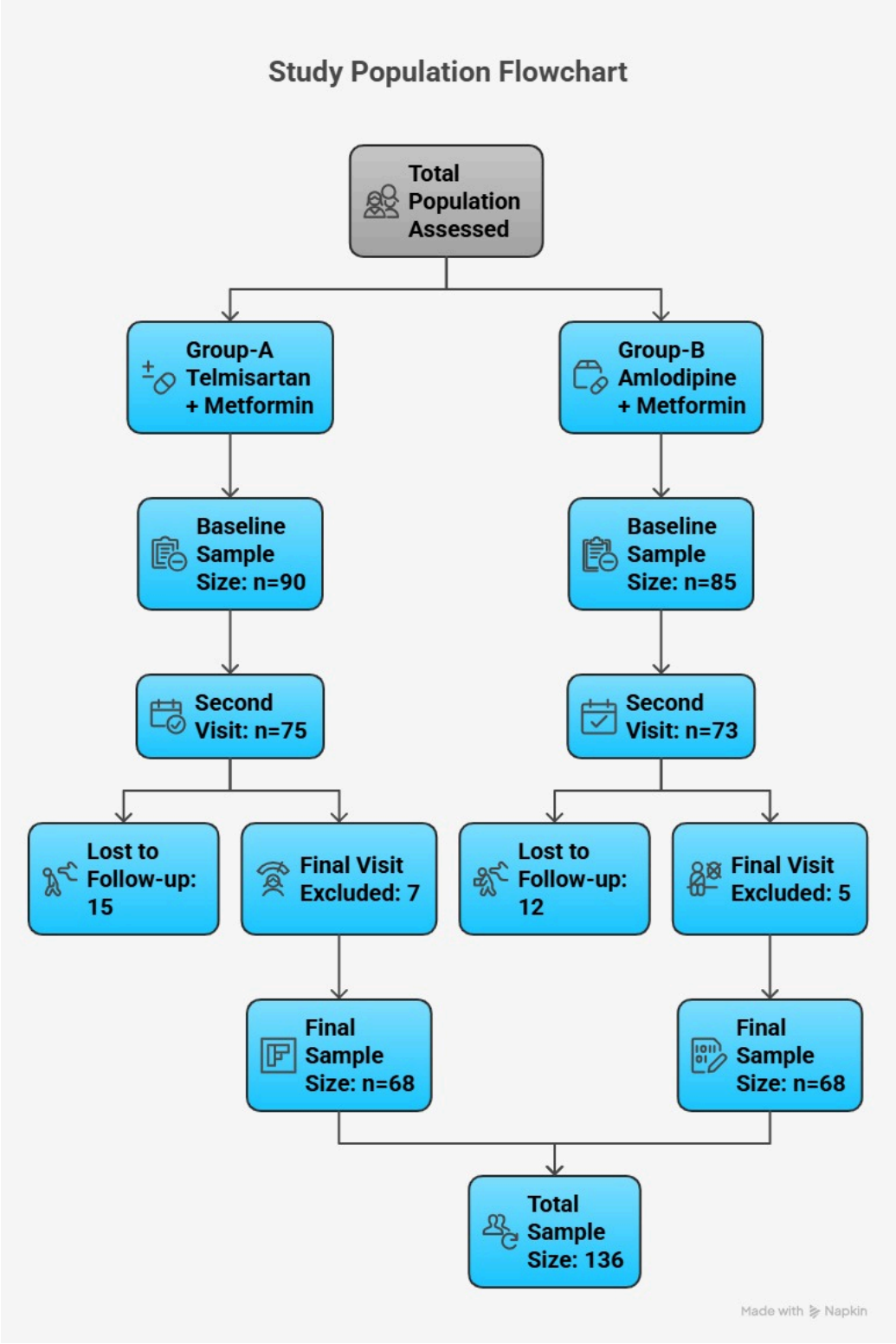


Figure 1

Study flowchart of participants