Novel low-dose triple single-pill combination shows efficacy and tolerability in two international trials

September 3 2024

Credit: Unsplash/CC0 Public Domain

A low-dose triple single-pill combination was effective at lowering blood pressure (BP) in two trials presented in a Hot Line session today at ESC

Congress 2024.

"Globally, most people treated for high BP do not achieve adequate control, primarily due to continued use of low-efficacy regimens including monotherapy. Single-pill combinations of different low-dose drugs hold promise for improving hypertension management by virtue of additive benefits, rapid action and a low risk of adverse events.

"We developed a triple single-pill combination, GMRx2, and tested this in a placebo-controlled trial to assess the product as a whole, and in a trial against three different dual therapies, to assess each component one by one. We are encouraged by the clinically meaningful BP improvements observed," explained Principal Investigator, Professor Anthony Rodgers of the George Institute for Global Health, University of New South Wales, Australia.

GMRx2 contains telmisartan, amlodipine and indapamide in three dose strengths: triple quarter doses (10 mg, 1.25 mg and 0.625 mg, respectively), triple half doses (20 mg, 2.5 mg and 1.25 mg) or triple standard doses (40 mg, 5 mg and 2.5 mg).

The international placebo-controlled double-blind trial investigated GMRx2 at quarter and half doses. The trial enrolled 295 adults with hypertension receiving 0–1 BP-lowering drugs. After a 2-week placebo run-in period during which any BP-lowering medication was stopped, patients with home systolic BP 130–154 mmHg were eligible for randomization in a 2:2:1 ratio to GMRx2 quarter dose, GMRx2 half dose or placebo. The primary efficacy outcome was the mean change in home systolic BP from baseline to week 4 and the primary safety outcome was treatment withdrawal due to an adverse event.

Mean clinic BP was 138/86 mmHg following the run-in period. At week 4, the placebo-corrected difference in home systolic BP was −7.3 mmHg

(95% confidence interval [CI] −4.5 to −10.8) with the GMRx2 quarter dose and −8.2 mmHg (−5.2 to −11.3) with the GMRx2 half dose. Clinic BP control (