

First detailed data of risk of using Rasilez with certain blood pressure-lowering drugs

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Researchers at St. Michael's Hospital have published the first detailed figures showing the risk of using the prescription drug Rasilez in combination with certain other blood pressure-lowering medications.

The pharmaceutical company Novartis terminated a large, international clinical trial of the drug last month after finding an increased incidence after 18-24 months of non-fatal strokes, renal complications, high levels of potassium in the blood and [low blood pressure](#).

As a result, Health Canada said on Dec. 22 that it would review the safety of Rasilez, the brand name for aliskiren.

Even before Novartis halted its clinical trial, Dr. Ziv Harel and other researchers at St. Michael's were examining the interaction between Rasilez and angiotensin converting enzyme (ACE) inhibitors or angiotensin [receptor blocker](#) (ARB) drugs.

After reviewing 10 large randomized clinical trials on the combination of these drugs, they found that patients taking Rasilez as well as an [ACE inhibitor](#) or ARB, had about a 50 per cent greater risk of developing hyperkalemia – high levels of potassium in the blood – than those taking only an ACE inhibitor or ARB.

As well, patients taking a combination of Rasilez plus an ACE inhibitor or ARB had a 70 per cent greater risk of developing hyperkalemia than those taking Rasilez alone. Hyperkalemia can lead to an irregular

heartbeat or increased risk of cardiac arrest.

Their analysis of the clinical trials was fast-tracked into publication this week in the *British Medical Journal*. It provided the first specific data of the risks of taking the drug combinations. Data was released from the halted [Novartis](#) trial, but a detailed analysis was not reported.

Previous research in 2008 found an increased risk of hyperkalemia and acute kidney failure in people taking a combination of ACE inhibitors and ARBs. So when Rasilez entered the market, clinicians were keen to replace one of those drugs in the combination. The number of prescriptions for Rasilez in Ontario rose from 56,602 in 2009 to 119,891 in 2010.

Dr. Harel, a nephrologist, said he was surprised to find no increased risk of kidney failure in patients taking Rasilez and an ACE inhibitor or ARB over those taking just one of the drugs. He said that might be because the short-term clinical trials they reviewed used a conservative definition of [kidney failure](#) or the patients were being monitored so closely that any sign of kidney damage would have been detected and treated quickly.

Dr. Harel said he believes that clinicians should offer alternatives to prescribing combinations of medications with a strong potential for life-threatening adverse events.

Provided by St. Michael's Hospital

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