- My name is Eline Ploumen, I'm from Thorax Centrum Twente in the Netherlands and I'm currently a PhD candidate. The name of the trial is the BIO-RESORT trial and the principal investigator is Clemens von Birgelen.

Rationale

In the past it was suggested that the durable polymer that is present in drug-eluting stents may cause ongoing inflammation when it was implanted in the coronaries. So the BIO-RESORT trial was designed to assess two biodegradable polymer stent against a durable polymer reference device and the thought was that after the degradation of the biodegradable polymer only a bare-metal stent would be left behind in the coronary. And this may give you an advantage in terms of adverse event rates following the PCI procedure.

Investigated Devices

So the two novel devices that were investigated were the Orsiro and Synergy. The Orsiro is an ultra thin strut cobalt-chromium device that is coated with a biodegradable polymer and eludes sirolimus. And the Synergy is a very thin strut device. It's made of platinum chromium and it's coated with a biodegradable polymer as well, but it eludes everolimus. And these devices were assessed against the Resolute Integrity, which is a durable polymer device, also made of cobalt-chromium, and it eludes Zotarolimus.

Trial Design and Patient Population

The trial was designed as a non-inferiority study and at one year non-inferiority was established for the Orsiro and Synergy versus the Resolute Integrity. And we assess all-comers patients, which means any reference vessel size or lesion length or lesion type was allowed. And any type of coronary syndrome was included in the trial. We included 3,514 patients, and they were all randomised in a one-to-one-to-one manner to one of the three study devices and randomization was stratified for diabetes. The trial was monitored and all adverse events were adjudicated by an independent clinical events committee.

Key Results

The key results of the trail are that at five-year follow-up, there was no difference for all-comers patients regarding target vessel failure for all three devices. So the safety and efficacy of Orsiro and Synergy versus Resolute Integrity at five years was established. Furthermore, in the high risk population of patients with diabetes, we also found no difference in safety and efficacy in the individual endpoints of target vessel failure. So that is target vessel MI, cardiac death and target vessel revascularization. We also found no significant differences for the three stents.

Stent Selection for Patients with Diabetes

Based on our trial we can not say that a specific stent should be selected for patients with diabetes. The trial was not powered to assess differences in the diabetics sub population, but we did stratify for diabetes at randomization, and we had quite a sizeable population of 200 diabetic patients for treatment arm. And we found that the safety endpoint cardiac death was lower in patients treated with Orsiro than patients treated with Resolute Integrity in the diabetic patients. So you may be inclined to think that the diabetic patients are somewhat better off with Orsiro. However, we cannot draw any definitive conclusions. As I mentioned, that there was no significant, no, there was no sufficient power to assess this in the trial.

Take-Home Messages

The take home messages are that the novel devices with the biodegradable polymer coating, so the Orsiro and the Synergy stents are safe and effective in all-comers patients, as well as in a high risk population with diabetes. We're always looking to further improve the outcome of patients treated with PCI.

Next Steps

I think there's still some ongoing development for novel devices, and we were always looking to investigate new devices that may cause slight improvements in the outcome of patients. And I think over time, you can see that the overall event rates following PCI have declined. Which is not only the effect of stent design, of course, but also of concomitant medication. But I think the next steps will always be to keep investigating the next iterations of stents that slightly improved outcome.