

12-month primary endpoint results of the BIO-RESORT trial, RCT Orsiro vs. Synergy and Resolute Integrity



Conclusions

- In this 3514 patient large, randomized, investigator-initiated, all-comers trial Orsiro demonstrated non-inferiority to Synergy and Resolute Integrity for the primary endpoint (TVF at 12 months: Orsiro 4.7 %, Synergy 4.7 %, Resolute Integrity 5.4 %, p for non-inferiority <0.0001)
- Orsiro, with its ultrathin struts and bioabsorbable polymer, additionally showed safety with a definite stent thrombosis rate of 0.3 % at 12 months, which was equally low in the other study arms
- These convincing results reconfirm those of previous Orsiro trials and adds to the solid foundation of clinical evidence that supports the use of Orsiro across a broad range of applications

Study design

All-comers, multi-center, assessor and patient-blinded, randomized, non-inferiority design

Principal Investigator

- Prof. Clemens von Birgelen, Enschede, Netherlands

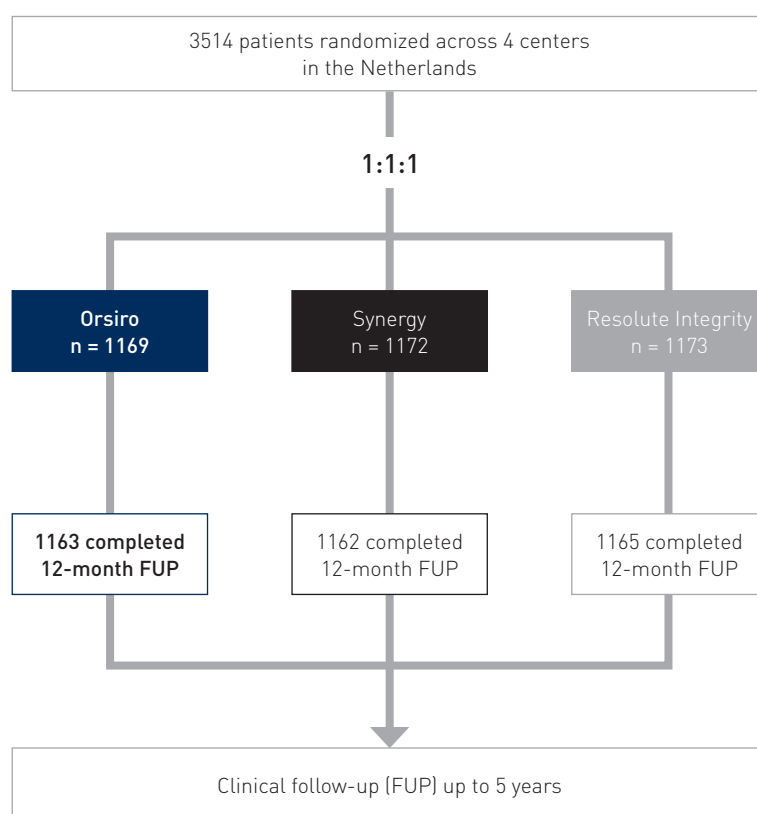
Endpoints

Primary endpoint

- Target Vessel Failure (TVF) at 12 months defined as the composite of cardiac death, target vessel-related Myocardial Infarction (MI), or Target Vessel Revascularization (TVR)

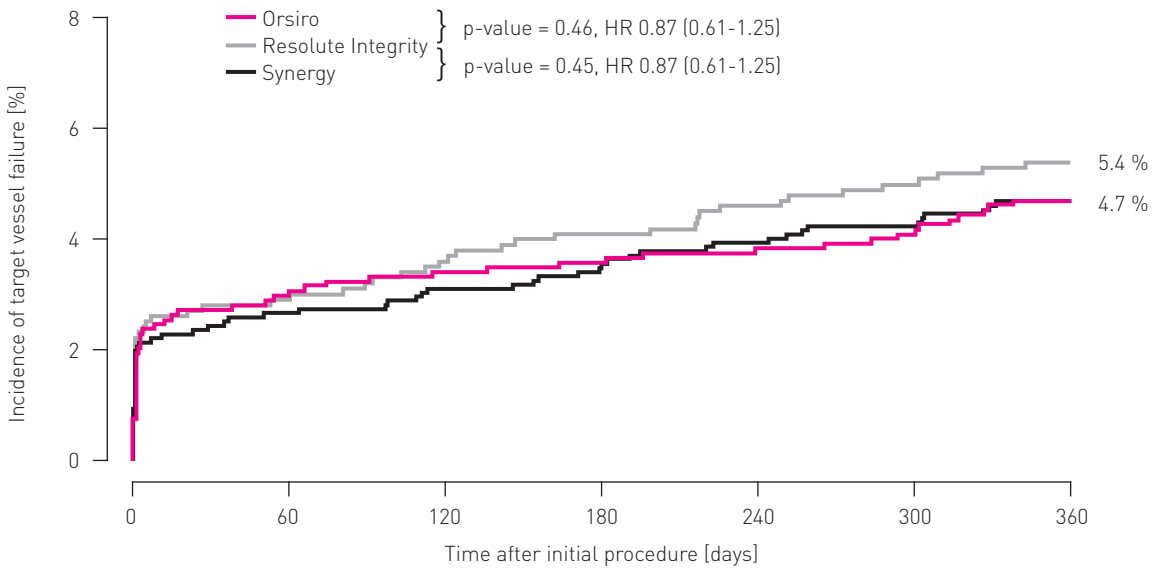
Prespecified secondary endpoints

- Components of the primary endpoint
- All-cause mortality
- Any Myocardial Infarction (MI)
- Clinically indicated Target Lesion Revascularization (TLR)
- Stent thrombosis



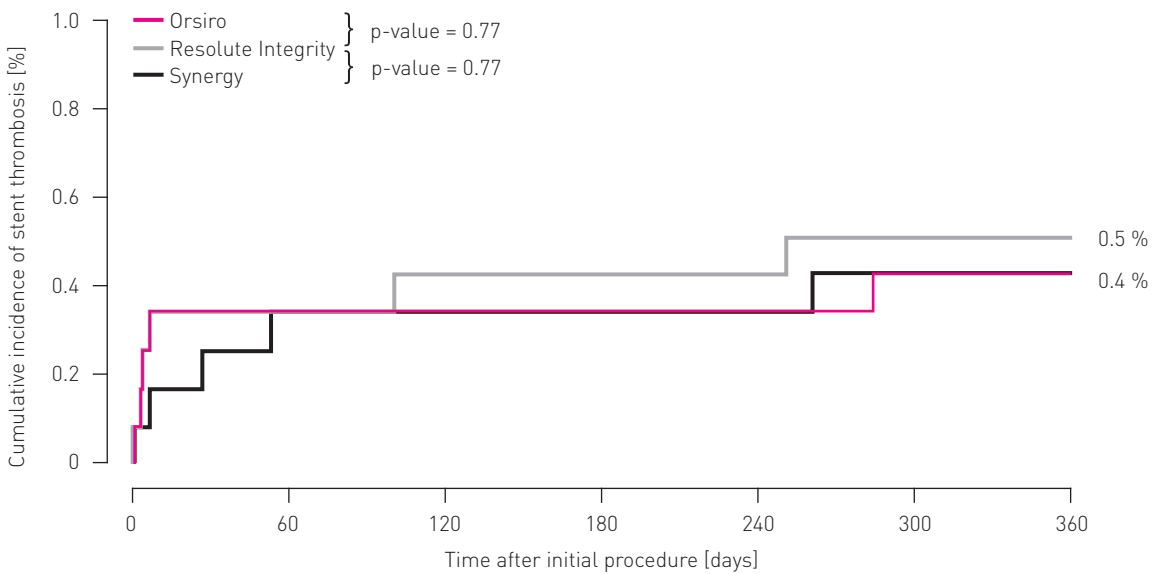
Primary endpoint

Target vessel failure^{1,2}



Stent thrombosis

Definite or probable stent thrombosis until 1-year follow-up^{1,2}



¹ von Birgelen C et al. BIO-RESORT (TWENTE III). A Prospective, Randomized Three-Arm Trial Comparing Orsiro, Synergy and Resolute Integrity in an All-Comers Population. TCT 2016. Oral presentation.

² von Birgelen C et al. Very thin strut biodegradable polymer everolimus-eluting and sirolimus-eluting stents versus durable polymer zotarolimus-eluting stents in allcomers with coronary artery disease (BIO-RESORT): a three-arm, randomised, non-inferiority trial. Lancet 2016. Online publication (10.1016. S0140-6736(16); 31920-1).