QualiMed®

A Q3 Medical Company

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Clinical Studies

Qualimed development has been founded on a sound clinical evaluation strategy that has produced a number of published studies that are available for your prevue. Please find below a list of our Cardiology, Peripheral Vascular Studies.

Cardiology

No.	Device/Study	Report/Publication	Patients	Outcome	Result
1	Stainless Steel Stent SC-Registry	Voigt et al 2000 (Kardiologie-Abstract) - Der Stainless Steel-Stent - Erste Erfahrungen und Ergebnisse	70	6mFU RR 17.1%	Stainless Steel Stent is safe with a low restenosis rate after 6 months
2	Stainless Steel Carbon PREVENT Study MC-RCT	Sick et al 2004 (DGK-Abstract) - Prospektiv randomisierte Vergleichsstudie PREVENT	396	6mFU, RR 18.0%, MACE 13.5%	Safe and effective compared to stainless steel stent
3	Cobalt Chromium Stent PASS Study MC-RCT	Park et al 2002 (Am J Cardiol-Abs) - Randomized Comparison Cobalt Chromium Stent - PASS-Study	230	21mFU, RR 11%	Cobalt Chromium Stent reduces the restenosis rate (11% vs 18%)
4	Cobalt Chromium Stent Study SC-Registry	Schukro et al 2003 (Int Con CAD) - Preliminary Results of ArthosInert Registry	121	8mFU, RR 8.2%, MACE 8.2%	Good clinical results and low restenosis rate
5	Cobalt Chromium Stent IRIS Trial MC-RCT	Fourrier J et al 2012 (Interim Report) - IRIS - Bioactive Carbonized Stent Trial	155	6mFU, MACE 11.5%, TLR 4.5%, RR 4.5%	This stent has shown an unexpected safety and efficacy outcome in all-comer population
6	Cobalt Chromium Stent AUSTRIAN Study MC-Registry	Gyöngyösi et al 2004 (CV News) - Results of Cobalt Chromium Stent Austrian Multicenter Registry	199	6mFU, LLL 0.42mm, MACE 13.2%	Stenting of small vessel with Cobalt Chromium Stent is safe. Good results with excellent late lumen loss
7	Cobalt Chromium Stent PIPA Study MC-Registry	Garcia E 2004 (Presentation) - PIPA Results	512	6mFU, MACE 5.4%	Very good short and midterm results in the treatment of lesions in small vessels
8	Cobalt Chromium Stent PIVER Study SC-Registry	Lefebvre et al 2004 (Cardiology) - Primary Results of PIVER (CoCr Small Vessel Registry)	71	1mFU, MACE 8.6%	PIVER indicate a very high success level in the difficult treatment of small vessels
9	Paclitaxel Drug Eluting Stent APPLAUSE Study SC-RCT	Grube et al 2006 (J Inv Card) - Evaluation of a new Paclitaxel-Eluting Stent - APPLAUSE Trial	30	6mFU, MACE 10.5% vs 40%	Early evidence in safety and efficacy of Paclitaxel Drug Eluting Stent at 6 months follow up
10	Paclitaxel Drug Eluting Stent ELITE Study MC-Registry	Glogar 2010 (Cardiology Int) - ELITE Registry Europe - non randomized multi-centre study	377	2yFU, TVR 7.8%	Paclitaxel Drug Eluting Stent is safe and effective. Superior to Taxus in historical comparison
11	MR Stent MR-MP Study SC-RCT	Wessely R et al 2007 (E Heart J) - Randomized Trial Rapamycin vs Paclitaxel Eluting Stent	91	9mFU, LLL 0.33mm vs 0.96mm, TLR 8.7% vs 26.7%, ST 0%	Both stent platforms proved safe. Rapamycin is more effective than Paclitaxel

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12	MR Stent MASTER Study SC-Registry	Mehilli J., Kastrati A. 2010 (Final Report) - MASTER Study Two Year Results (Itrix vs Cypher)	224	2yFU, ST 0%, MACE 20.5%	The stent has an excellent safety and efficacy profile. Both lack of stent thrombosis and lack of late restenosis catch-up may suggest a benefit with this platform
13	MR Stent PILOT OCT Study SC-RCT	Tada T, Byrne R 2012 (DHZM Report) - PILOT - 4 months follow-up report, Tada T et al 2012 (JACC) - Differential Vascular Healing Patterns with biodegradable SES	15	4mFU, No ST, 0% >30% uc struts vs 28%, 0% map struts	MR stents were associated with enhanced vascular healing at 4 months
14	Aspiration Catheter	Multicentre trial	19	90% success rate in acute	Aspiration Catheter fulfils guideline for acute treatment in coronaries

Peripheral Vascular

No.	Device/Study	Report/Publication	Patients	Outcome	Result
1	Stainless Steel Stent SC-Registry	Voigt et al 2000 (Kardiologie-Abstract) - Der Stainless Steel-Stent - Erste Erfahrungen und Ergebnisse	94	6mFU RR 17.1%	Stainless Steel Stent is safe with a low restenosis rate after 6 months
2	Self-expanding peripheral stent POLARIS	Q3 POLARIS REGISTRY Principal Investigator – Dr. Hans Krankenberg MD	95	Acute procedural success (≤30% stenosis and the absence of floe limiting dissection or major adverse events within 72h of the index procedure, Peripheral Academic Research Consortium (PARC) (1) was achieved in 93.7% (74/79) of the patients, and procedural success (increase in ankle brachial index ≥0.1 from baseline) at 30 days in 86.2% (56/65). Averaged symptom classification changed from Rutherford category 2.8 at baseline to 0.3 at 30 days.	We preliminarily conclude that the treatment of superficial femoral artery lesions with the POLARIS stent system in a real world setting is effective up to 30 days. So far, no safety concerns were raised

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