MILES UK Registry

A study to evaluate the safety and efficacy of the BioMime sirolimus eluting coronary stent system in all comers real world population with coronary artery stenosis in United Kingdom

Study Design

- Prospective, Multicenter, Single Arm, Observational Clinical Registry
- 14 centres in United Kingdom

Integrated Research Application System No.	135437
Study Objectives	• Primary objectives: The primary objective of this study is to evaluate the Safety and Efficacy of BioMime Sirolimus Eluting coronary Stent System in real world all comers Population • Secondary objectives: 1) To evaluate frequency of Target Vessel Failure 2) To evaluate the efficacy of the device by evaluating the frequency of Clinically Driven Target Vessel Revascularization 3) To evaluate clinical safety of device in terms of Deaths and Myocardial Infarction up to 2 years 4) To evaluate Stent Thrombosis up to 2 years
Primary Endpoints	• Efficacy: Rate of Target Vessel Failure at 9 months • Safety: Rate of Stent Thrombosis (ARC "definite" or "probable") in presence of dual antiplatelet therapy
Secondary Endpoints	• Cumulative Target Vessel Failure at 1, 9, 12 and 24 months • Target Lesion Revascularization at 1, 9, 12 and 24 months • Major Adverse Cardiac Events at 1, 9, 12 and 24 months • Frequency of Stent Thrombosis a) Acute (0-24 hours after stent implant) b) Sub acute (24 hours to 1 month after stent implant) c) Late (1 month to 1 year after stent implant)

	d) Very Late (Beyond 1 year after stent Implant) e) By ARC definitions: Definite, Probable and Possible, at all follow up visits
Clinical Sites	14 centres in United Kingdom
Sample Size	750 subjects
Follow-Up	Clinical/Telephonic follow-up at 30 days, 9 months, 1 year, and 2 years
Study Duration	Study start date October 2013 Estimated study completion October 2020

❖ References

Integrated Research Application System (IRAS) No.: 135437