

Melange BRS-1 Study

A study to evaluate safety and performance of Melange BRS Sirolimus Eluting BioResorbable Peripheral Scaffold System for use as an adjunct to percutaneous transluminal renal angioplasty of atherosclerotic *de novo* or restenotic lesion of the renal artery

Study Design

- Prospective, multicentre, open label clinical study
- 45 subjects to be enrolled at 10 sites across India

	Study Highlights
CTRI No.	CTRI/2017/10/010120
Study Objective	To determine safety and performance of Melange BRS Sirolimus Eluting BioResorbable Peripheral Scaffold System in the treatment of renal artery stenosis in patients with atherosclerotic disease of the renal arteries
Safety Endpoint	<ul style="list-style-type: none"> • Major Adverse Events
Performance Endpoints	<ul style="list-style-type: none"> • Acute device success [Time Frame: From beginning of index procedure to end of index procedure] • Acute procedure success [Time Frame From beginning of index procedure to end of index procedure] • Mean reduction in systolic/ diastolic blood pressure [Time Frame: Baseline, 1 month \pm14 days, 6 Months \pm28 days, 12 months \pm28 days, 2, 3, 4, and 5 years \pm28 days follow-up] • Change in Antihypertensive [Time Frame: at baseline, 1 month, 6 months, 12 months, 2 years, 3 years, 4 years and 5 years] • Change in Renal Function [Time Frame: baseline, post-procedure, 1 month, 6 months, 12 months, 2 years, 3 years, 4 years and 5 years]
Clinical Sites	10 sites across India
Sample Size	45 subjects
Follow-Up	<ul style="list-style-type: none"> • Follow-up visits at 1 month, 6 months, 9 months, 12 months, 2 years, 3 years, 4 years and 5 years • QCA at baseline and 6 months

Study Duration

Study start date February 2018
Estimated completion June 2025

❖ References

1. Clinical Trial Registry- India (CTRI): CTRI/2017/10/010120
<http://ctri.nic.in/Clinicaltrials/pmaindet2.php?trialid=15322&EncHid=&userName=>
2. Furer A, Gasior P, McGregor J, Palmieri T, Conditt G, Granada J, Kaluza G. TCT-844 Safety and Feasibility of Sirolimus Eluting Bioresorbable Stents in Porcine Renal Arteries–90-Day Angiographic and OCT study in Normal Swine. Journal of the American College of Cardiology. 2016 Nov 1;68(18 Supplement):B341.