

# MOZEC SEB PTCA-1 Study

A study to evaluate the safety and performance of MOZEC Sirolimus Eluting Percutaneous Transluminal Coronary Angioplasty Balloon dilatation catheter for native coronary artery disease in daily clinical practice

## Study Design

- Prospective, multicentre, real world study
- 123 subjects to be enrolled at 09 sites across India

	<b>Study Highlights</b>
<b>CTRI No.:</b>	CTRI/2017/03/008002
<b>Study Objective</b>	To evaluate the safety and performance of MOZEC Sirolimus Eluting Percutaneous Transluminal Coronary Angioplasty Balloon dilatation catheter for native coronary artery disease in daily clinical practice
<b>Safety Endpoint</b>	<ul style="list-style-type: none"><li>• Major Adverse Cardiac Events</li></ul>
<b>Performance Endpoints</b>	<ul style="list-style-type: none"><li>• Change in Late Lumen Loss</li><li>• Clinical success</li><li>• Device Success</li><li>• User rating on technical properties</li></ul>
<b>PK Endpoints</b>	<ul style="list-style-type: none"><li>• Time taken to reach to maximum concentration in blood after deployment of the MOZEC SEB.</li><li>• Maximum concentration of the drug obtained in peripheral venous blood</li><li>• Mean half life period of the drug in venous blood</li><li>• Area under curve of the blood drug concentration</li><li>• Time taken for drug to go below detectable levels in venous blood sample</li></ul>
<b>Clinical Sites</b>	09 sites across India
<b>Sample Size</b>	123 subjects
<b>Follow-Up</b>	Follow-up visits at 1 month, 6 months, 12 months and 24 months
<b>Study Duration</b>	Study start date June 2017 Estimated completion December 2020

## ❖ References

1. Clinical Trial Registry- India (CTRI): CTRI/2017/03/008002  
<http://ctri.nic.in/Clinicaltrials/showallp.php?mid1=16876&EncHid=&userName=CTRI/2017/03/008002>