Obtura VCD-1 Study

A study to compare and evaluate hemostasis and ambulation in patients who have undergone diagnostic or interventional catheterization procedures with 6F and 8F Obtura VCD against manual compression method

Study Design

- A prospective, single-blind, multi-center, randomized clinical study
- Approximately 218 patients will be randomly enrolled in a 1:1 ratio

	Study Highlights
CTRI No.	CTRI/2018/01/011597
Study Objective	To compare and evaluate hemostasis and ambulation in patients who have undergone diagnostic or interventional catheterization procedures using a standard 6F/7F/8F introducer sheath with up to 12 cm working length with 6F and 8F Obtura VCD against manual compression method.
Primary Endpoints	• Time to Hemostasis: Between 0-60 Minutes [Time Frame: At puncture closure] • Percentage of Patients With Obtura VCD Deployment Success [Time Frame: At puncture closure]
Performance Endpoints	• Time to Ambulation • Number of Patients with Vascular Closure Related Adverse Events • Vascular Closure Related Adverse Events noticed using Duplex Sonography • Technical Success Rate
Clinical Sites	08 sites across India
Sample Size	218 patients [Obtura Vascular Closure Device (n=109) Vs. Manual compression (n=109)]
Follow-Up	Clinical/Telephonic follow-up at 2 Weeks (±3days), 1 month (±7 days) and 3 months (±7 days)
Study Duration	Study start date September 2018 Estimated completion June 2019

❖ References

1. Clinical Trial Registry- India (CTRI): CTRI/2018/01/011597 http://ctri.nic.in/Clinicaltrials/showallp.php?mid1=20819&EncHid=&userName=CTRI/2018/01/011597