MITSU Polyglactin 910 Suture Study

A study to evaluate safety and efficacy of MITSU Polyglactin 910 Suture with coated Vicryl Polyglactin 910 Suture in closure of surgical incision

Study Design

- Prospective, multi-centre, randomized-controlled, single-blind, comparative study
- 122 subjects enrolled at 3 sites across India

CTRI No.	CTRI/2017/01/007717
Study Objective	To evaluate the safety and efficacy of MITSU Polyglactin 910 Suture with Coated Vicryl Polyglactin 910 Suture in closure of surgical incision
Safety Endpoint	• Overall wound dehiscence Wound dehiscence is defined as a complete wound disruption that needed emergent reoperation
Efficacy Endpoints	• Rate of Surgical Site Infection (SSI) resulted from suturing material as per judgment of study investigator • Hospital length of stay
Clinical Sites	3 sites in India
Sample Size	122 subjects [MITSU Polyglactin 910 Suture (Meril Endo-Surgery Pvt. Ltd): 61 subjects; Coated Vicryl Polyglactin 910 suture (Ethicon USA, LLC): 61 subjects]
Follow-Up	Clinical follow-up was scheduled at 14 days (±2 days), 30 days (±7 days) and 6 months (±28 days)
Study Duration	Study started on January, 2017 Study completed on February, 2018

❖ Reference:

1. Clinical Trial Registry- India (CTRI): CTRI/2017/01/007717 http://ctri.nic.in/Clinicaltrials/showallp.php?mid1=16381&EncHid=&userName=CTRI/2017/01/007717
2. Dixit A, Nadkarni P, Shah V, Patel B, Turiya PK, Thakkar A. Evaluation of safety and efficacy of polyglactin 910 suture in surgical incision closure: clinical study protocol for a randomized controlled trial. International Journal of Clinical Trials. 2018. 2018;5(1):6.