CONFORTA Study –Newsletter #12

Oct-2022

Clinical study to evaluate the Safety, Efficacy and Cost Analysis of the GORE® *TAG*® Conformable Thoracic Stent Graft with *ACTIVE* ***CON****TROL* system **FOR** patients with descending **T**horacic **A**ortic pathologies ***(CONFORTA)***

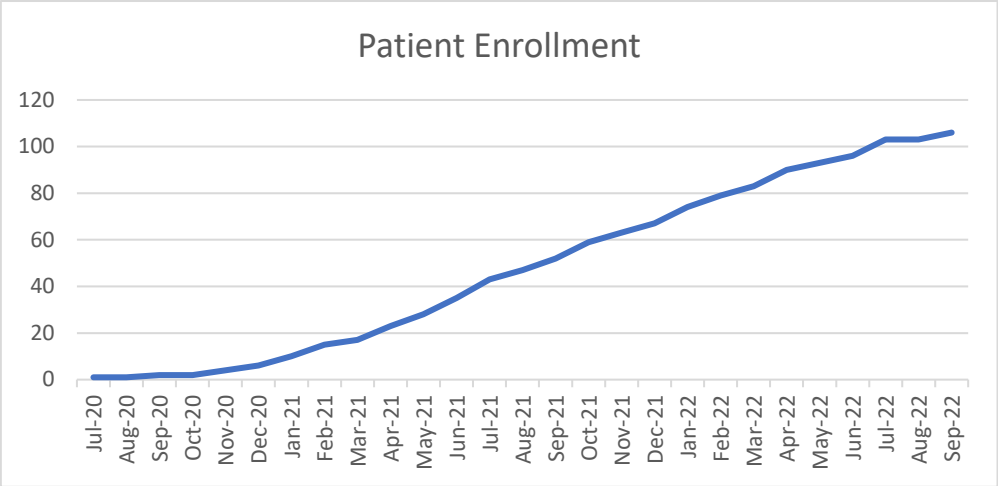
Dear Investigators, Dear Study Teams,

Many thanks for your efforts and participation in the CONFORTA study so far!

We are proud to announce that we finally reached out 100 patients! Currently, a total of 110 patients have been enrolled. **None of us is as good as all of us put together.**

As we all know, enrollment has undergone a significant slowdown due to pandemic emergency caused by COVID-19. Now it is time to increase the slope in the graph below.

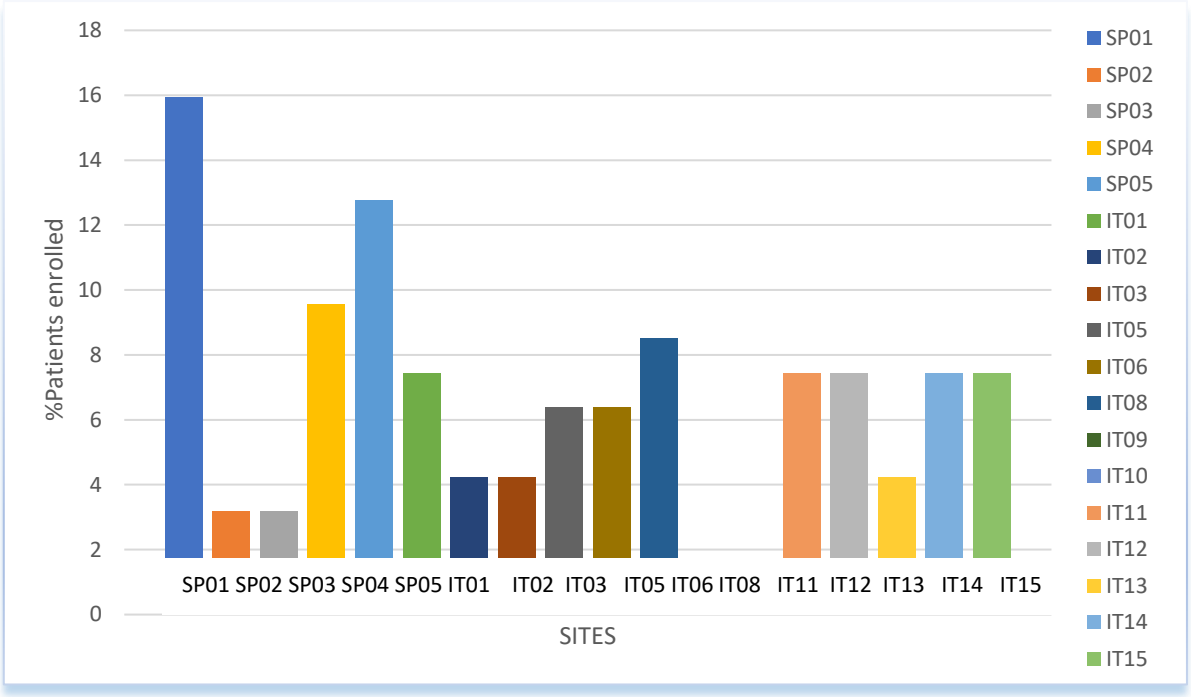
We would like to remind you that recruitment will continue to be open and competitive until reaching 200 patients.



We are pleased to announce that:

- **Five sites enrolled their patients in Spain**:
  - ✓ Dr. Riambau (Hospital Clinic – Barcelona): 15 patients;
  - ✓ Dr. Mosquera (Hospital Clínico Universitario of Santiago): 5 patients;
  - ✓ Dr. Alonso (Hospital Universitario Central de Asturias (HUCA)): 3 patients;
  - ✓ Dr. Salmerón (Hospital Clínico San Cecilio – Granada): 9 patients;
  - ✓ Dr. Marzo (Hospital Universitario Miguel Servet – Zaragoza): 12 patients.

- **Eleven sites enrolled their patients in Italy**:
  - ✓ Prof. Trimarchi (IRCCS Ca' Granda Ospedale Maggiore – Milano): 7 patients;
  - ✓ Prof. Camparini (Azienda Ospedadliera Brotzu – Cagliari): 4 patients;
  - ✓ Prof. Pulli (Azienda Ospedaliero Universitaria Careggi – Firenze): 4 patients;
  - ✓ Prof. Piffaretti (Ospedale di circolo di Varese – Varese): 6 patient;
  - ✓ Prof. Tshomba (IRCCS Agostino Gemelli – Roma): 6 patients;
  - ✓ Prof. Tolva (ASST Ospedale Metropolitano Niguarda – Milano): 8 patients;
  - ✓ Prof. Pratesi (IRCCS Ospedale San Martino – Genova): 7 patients;
  - ✓ Prof. Angiletta (Azienda Universitaria Ospedaliera Consorziale – Bari): 7 patients;
  - ✓ Prof. Benedetto (Azienda Ospedaliero Universitaria Martino –Messina): 4 patients;
  - ✓ Prof. Antonello (Azienda Ospedaliera di Padova – Padova): 7 patients;
  - ✓ Prof. Bonardelli (ASST Spedali Civili di Brescia – Brescia): 7 patients.



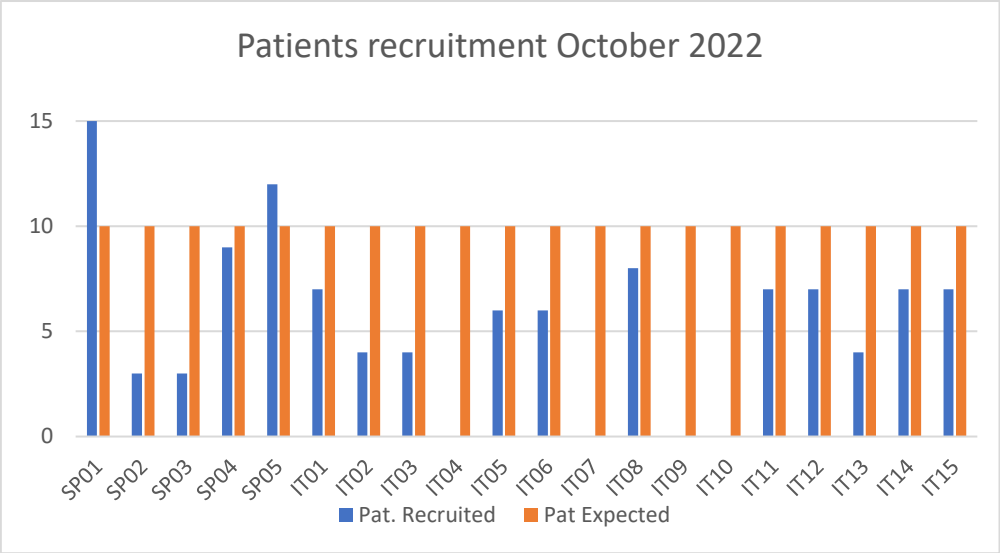
Total of patients enrolled

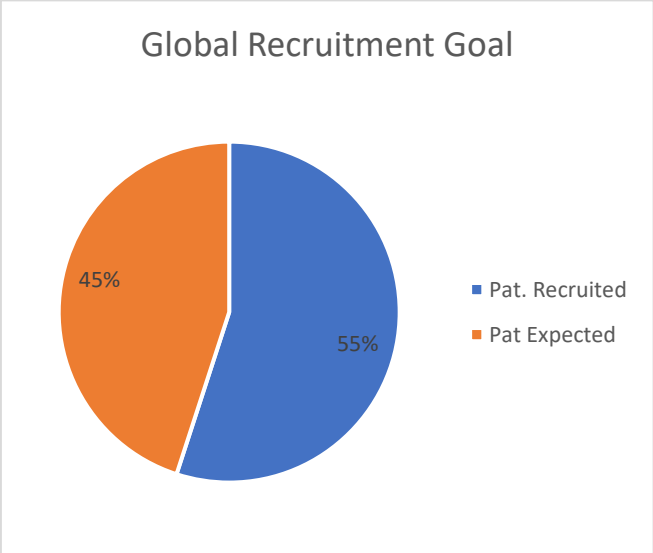
Italy	Spain
66	44

Pending issues

Italy

ASST Papa Giovanni XXIII – Prof. Maraglino: Contract under site review





Overall, 110 subjects were enrolled in our study so far, 55% of our global recruitment goal of 200.

Reminder

Due to the inconveniences that have occurred during the last monitoring visits carried out in the Italian sites, we remind you the importance of having well-defined source documents.

Source data is defined in GCP guidelines as **"All information contained in the original records and certified copies of the original records of clinical findings, observations, or other activities of a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in the source documents (original records or**

certified copies)". In order to perform monitoring activities, the monitor needs to have access to source documents.

Remember that **site staff can use "worksheets" to record data needed in the study, especially data that are not collected in routine clinical practice**. Worksheets are available for all sections of the eCRF and site staff can use them as a source document as long as it is updated in Source Data Location List.

Please do not hesitate to contact the monitors to clarify this issue!

New study team members

Giulia Barbera and Amalia Benigno are the new CRAs for Italian team
Irene Delgado is the new CRA for Spanish team

Best regards,

Your Endovascular Foundation and Leon Research project team.

Contact Information

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