CONFORTA Study –Newsletter #05

05-Jul-2021

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!

We are pleased to announce that:

- **Four sites enrolled their patients in Spain**:
  - ✓ Dr. Riambau (Hospital Clinic – Barcelona): 4 patients;
  - ✓ Dr. Alonso (Hospital Universitario Central de Asturias (HUCA)): 2 patient;
  - ✓ Dr. Salmerón (Hospital Clínico San Cecilio – Granada): 5 patients;
  - ✓ Dr. Marzo (Hospital Universitario Miguel Servet – Zaragoza): 3 patients.

- **Eight sites enrolled the first patients in Italy**:
  - ✓ Dr. Camparini (Botzu Hospital – Cagliari): 5 patients;
  - ✓ Prof. Tshomba (Hospital Gemelli – Rome): 1 patient;

- ✓ Prof. Pulli (Hospital-University consortium Polyclinic - Bari): 3 patients;
- ✓ Prof. Palombo (San Martino Hospital – Genoa): 4 patients;
- ✓ Prof. Trimarchi (IRCCS Ca' Granda – Milan): 1 patient;
- ✓ Prof. Pratesi (Careggi Hospital – Florence): 1 patient;
- ✓ Prof. Tolva (Niguarda Hospital – Milan): 1 patient
- ✓ Prof. Antonello (Padua University-Hospital – Padua): 1 patient

Total of patients enrolled:

Italy	Spain
17	**14**

All EC approval and the study contracts were obtained – It is pending to be obtain the IT05 EC approval- Achievement Goal, Mid-End of July 2021

Pending issues

Italy

1. **Ospedale di Circolo di Varese-Prof. Gabriele Piffaretti:** EC response received on 30 June 2021 requesting clarifications, response with clarifications to be sent within July 2021.
2. **Ospedale Papa Giovanni XXIII - Dr. Cosimo Maraglino:** Final EC Approval obtained, contract under revision;
3. **Azienda Ospedaliera San Camillo-Forlanini - Prof. Nicola Mangialardi:** Waiting for enrollment of the first patient;
4. **Azienda Ospedaliera Policlinico Universitario "G. Martino" - Prof. Filippo Benedetto:** Waiting for the enrollment of the first patient.
5. **A.O. Spedali Civili di Brescia - Prof. Stefano Bonardelli:** Waiting for the enrollment of the first patient.

Spain

1. **Hospital Clínico Universitario of Santiago – Dr. Nilo Javier Mosquera Arochena:** Waiting for the enrollment of the first patient.

Dear Investigators,

Dear Study Teams,

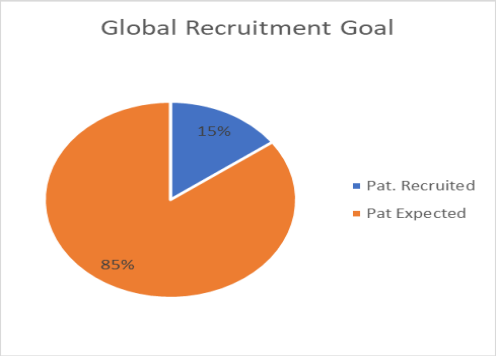
Many thanks for your efforts and participation in the CONFORTA study so far!

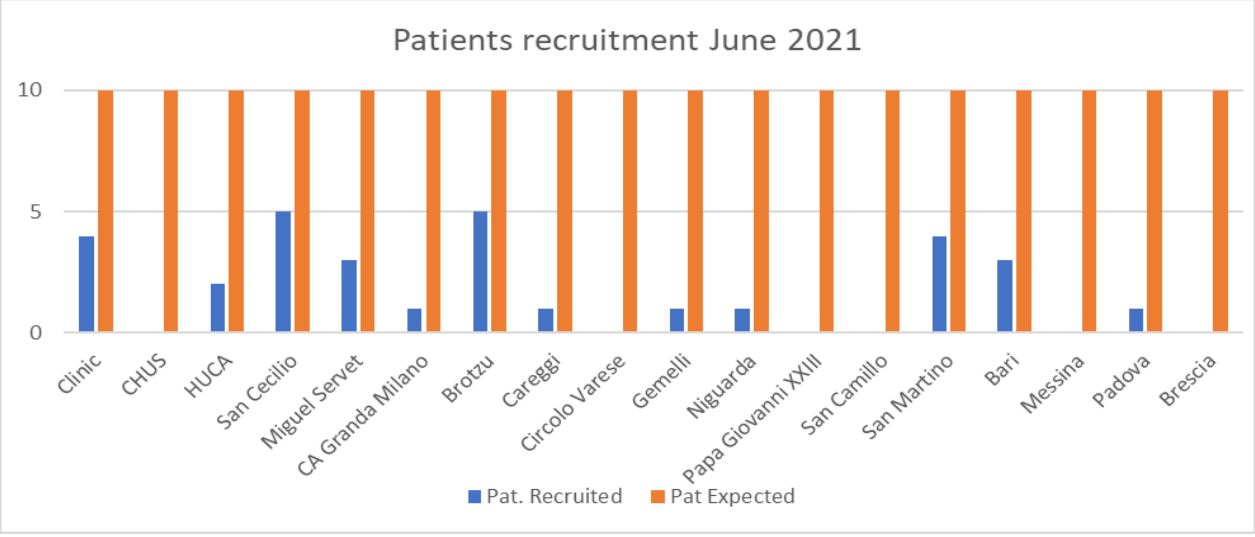
As we all know, enrollment has undergone a significant slowdown due to the health emergency brought by the pandemic caused by COVID-19.

As per study protocol, the goal of the study was to enroll 200 patients in 18 months of recruitment between 2020 and 2021.

The sponsor has decided to make an extension of the recruitment period and it is expected to recruit 100 (75 more patients) until second term of 2022 and complete the enrollment in 2023.

Overall, 31 subjects were enrolled in our study so far, 15.5 % of our global recruitment goal of 200.





To reach the primary endpoint analysis it would be necessary that at least 50 patients have completed 12month follow-up visit, unfortunately we have not reached this goal. It is expected that first patient included in the study (SP01-001) will complete the 12months follow-up visit by July 2021.

Best regards

Contact Information

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