

SYNOPSIS CLINICAL INVESTIGATIONS

TITLE

Clinical trial evaluating medical-grade polycaprolactone-PCL Pectus scaffold implantation with autologous fat grafting for pectus excavatum camouflage (IT).

Studio clinico per la valutazione dell'impianto di uno scaffold custom-made in policaprolattone (PCL), usato in combinazione con trasferimento di tessuto adiposo autologo, per la correzione del petto escavato.

COUNTRY/CURRENT STATUS

Italy/Waiting for approval

PROJECT NUMBER

2021-PEC-002

NUMBER OF PATIENTS

10

SYNOPSIS

The 2021-PEC-002 clinical will be conducted in Florence, Italy under the supervision of the principal investigator Dr. Flavio Facchini. Up to ten patients of minimum 14 years old for female and minimum 16 years old for male will be enrolled at Meyer Hospital and will be followed up for two years after surgery. The operation involves the insertion of the investigational device, a custom-made 3D printed polycaprolactone scaffold, in the thorax region in combination with autologous fat grafting (AFG) to camouflage pectus excavatum defects in patients unsuitable for conventional treatment with stable cardio-respiratory function. The objective of the study is to demonstrate the safety and clinical performance of the investigational device for large volume soft tissue reconstruction in pectus excavatum camouflage.