



The GIOTTO 4 Study

GISE registry of transcatheter treatment of mitral valve regurgitation with the MitraClip G4



We are very pleased to announce you the **FIRST PATIENT ENROLLED!** (20.02.2023)

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Gruppo San Donato

Echocardiographic manual: attached to this email you can find the final version of the echocardiographic manual, it will be accessible also in the eCRF in order to guide you during the data collection of the echocardiographic assessment

5 ACTIVE CENTERS

POLICLINICO SAN DONATO	10 PTS ENROLLED →
SAN RAFFAELE (U.O emodinamica)	0 PTS ENROLLED →
SAN RAFFAELE (U.O cardiocirurgia)	0 PTS ENROLLED →
POLIAMBULANZA	0 PTS ENROLLED →
MIULLI	0 PTS ENROLLED ↓

SUBMISSION STATUS



7

CONTRACT NEGOTIATION/DOCUMENTS SUBMITTED

4

DOCUMENTS TO BE SUBMITTED



Prof. Francesco Bedogni



Prof. Giuseppe Tarantini

Principal Investigators

Prospective and retrospective, non-interventional, multi-center national study

IMPORTANT!: RETROSPECTIVE ENROLLMENT WINDOW STARTS ON OCTOBER 13, 2022

PRIMARY ENDPOINT:

The primary study outcome consists of two co-primary outcomes: the 30-day and 1-year mitral regurgitation grade

OBJECTIVE:

To evaluate the safety and effectiveness of MitraClip G4 in the Italian practice

TIMELINE



First subject enrolled on 20.02.2023



Enrollment target: 923 patients



Enrollment period: 1 year and 6 months

SCHEDULE OF INVESTIGATIONS

Procedure/Interval	Screening	Baseline	Procedure	Discharge	30 days (+14 days)	1 year (+45 days)	2 years (+45 days)	3 years (+45 days)	4 years (+45 days)	5 years (+45 days)
Inclusion/Exclusion criteria	X									
Heart Team	X									
Informed Consent	X									
Clinical history		X								
Vital signs		X		X	X	X		X		X
Clinical examination		X		X	X	X		X		X
NYHA		X		X	X	X	X	X	X	X
6MWT*		X			X	X		X		X
QoL*		X			X	X		X		X
Friality*		X								
Laboratory tests including BNP/NTpro-BNP*		X		X	X	X		X		X
12-leads EKG		X		X	X	X		X		X
Medications		X		X	X	X	X	X	X	X
Transesophageal echocardiography		X	X							
Transthoracic Echocardiography		X		X	X	X		X		X
RHC**		X								
Adverse events			X	X	X	X	X	X	X	X

*required only if it is included in the normal clinical practice of the center

** Should be performed to assess pre-capillary pulmonary hypertension if baseline systolic pulmonary pressure is >70 mmHg.

Committee members

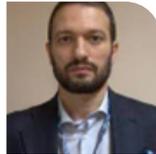
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Department of Cardiac, Thoracic, Vascular Sciences and Public
Health
University of Padova



Prof. Francesco Bedogni

Principal Investigators

Prof. Giuseppe Tarantini



GUIDELINES

We recommend you to follow the general guidelines described below:

- **Upload the signed informed consent by the patient in the trial master files in redcap before starting data compilation in the eCRF**
- **ECHO images must be uploaded in the eCRF, before uploading, the images must be anonymized as indicated in the chart**
- **The follow-ups scheduled at 2 and 4 years can also be performed by telephone, we recommend that you respect the execution windows reported for each patient in the corresponding follow-up chart**

Contact Us



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 <https://edc01.unipd-ubep.it/> (eCRF e Trial Master File)