

SHOCKCALCIUM

An Investigator Driven Italian Allcomers Registry of Calcified Lesions Treated with Intravascular Lithotripsy



STUDY DESIGN AND PRIMARY ENDPOINT

Prospective, non-interventional, multi-center international study

**PRIMARY ENDPOINT:
Target lesion failure (TLF) at 1year**

Secondary safety endpoints:

in Hospital Target lesion failure (TLF); Target Lesion Failure at 30 days; definite or probable stent thrombosis; procedural angiographic safety endpoints.

Secondary effectiveness endpoints:

device crossing and IVL delivery success; angiographic success; QCA outcome; Imaging outcome.

TIMELINE



First subject enrolled on 16.09.2022

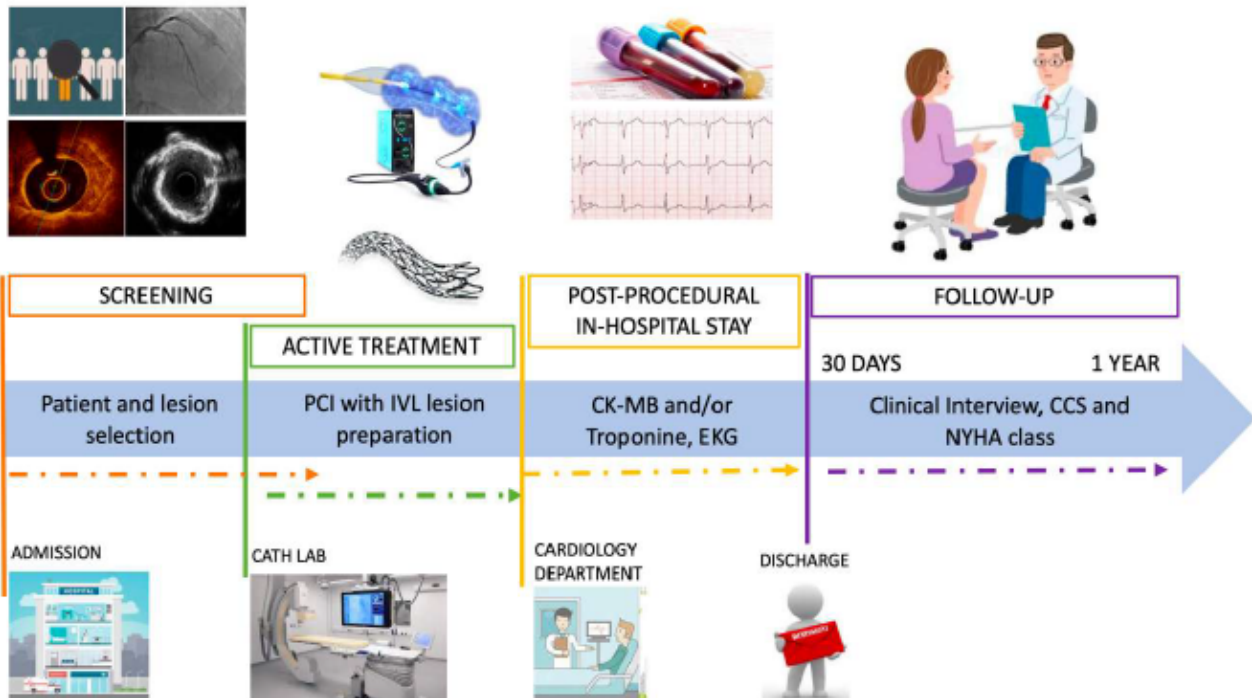


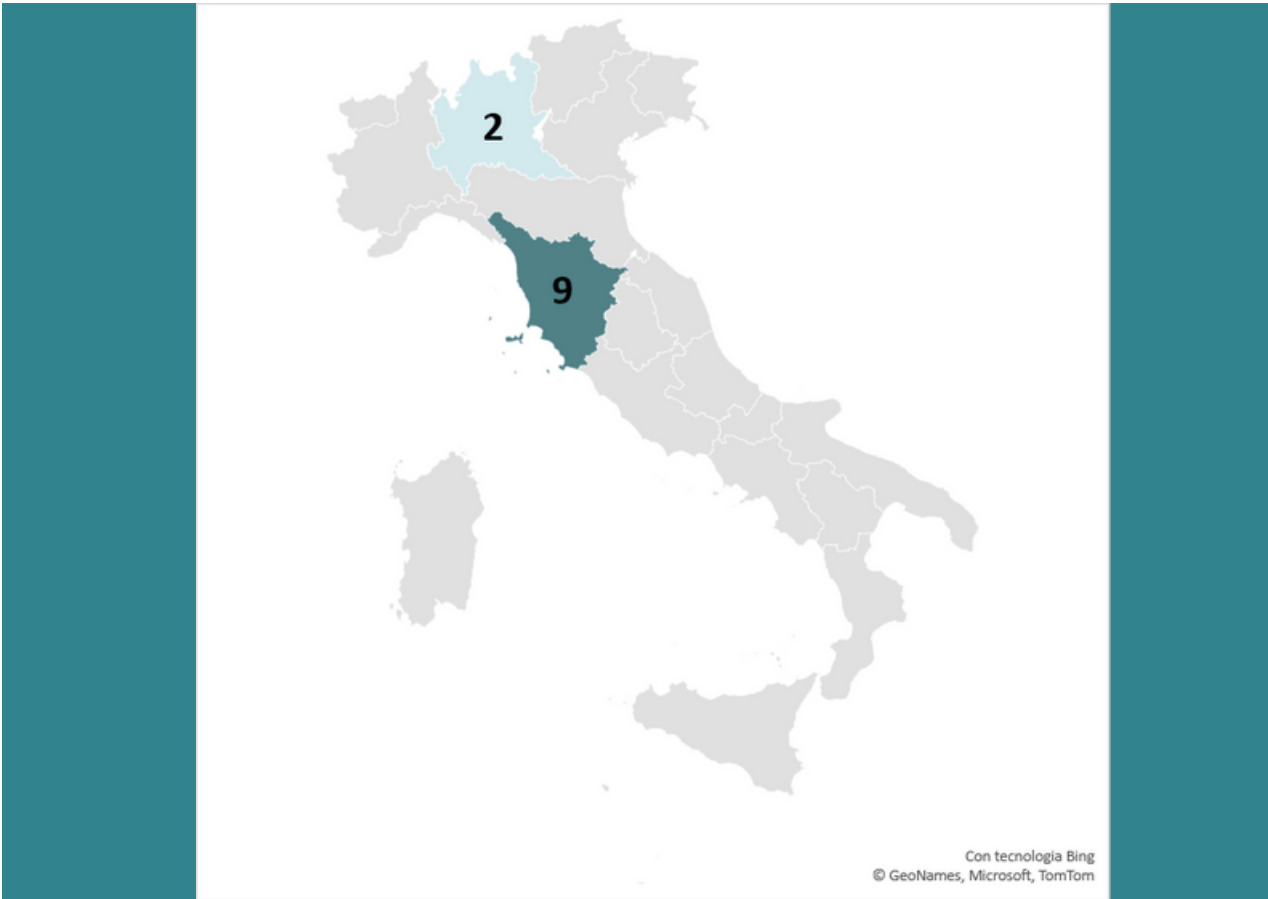
Enrollment target: 2000 patients



Enrollment period: 2 years

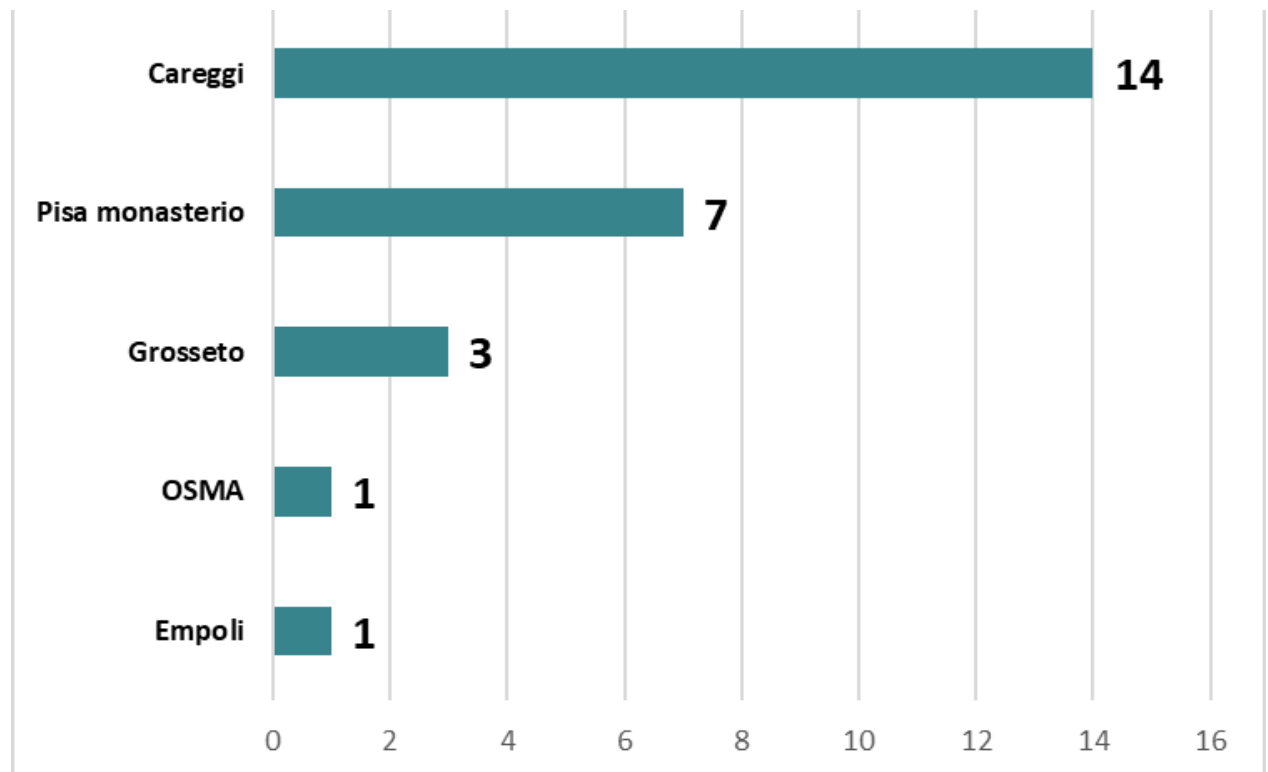
FLOW CHART





11 ACTIVE ITALIAN CENTERS

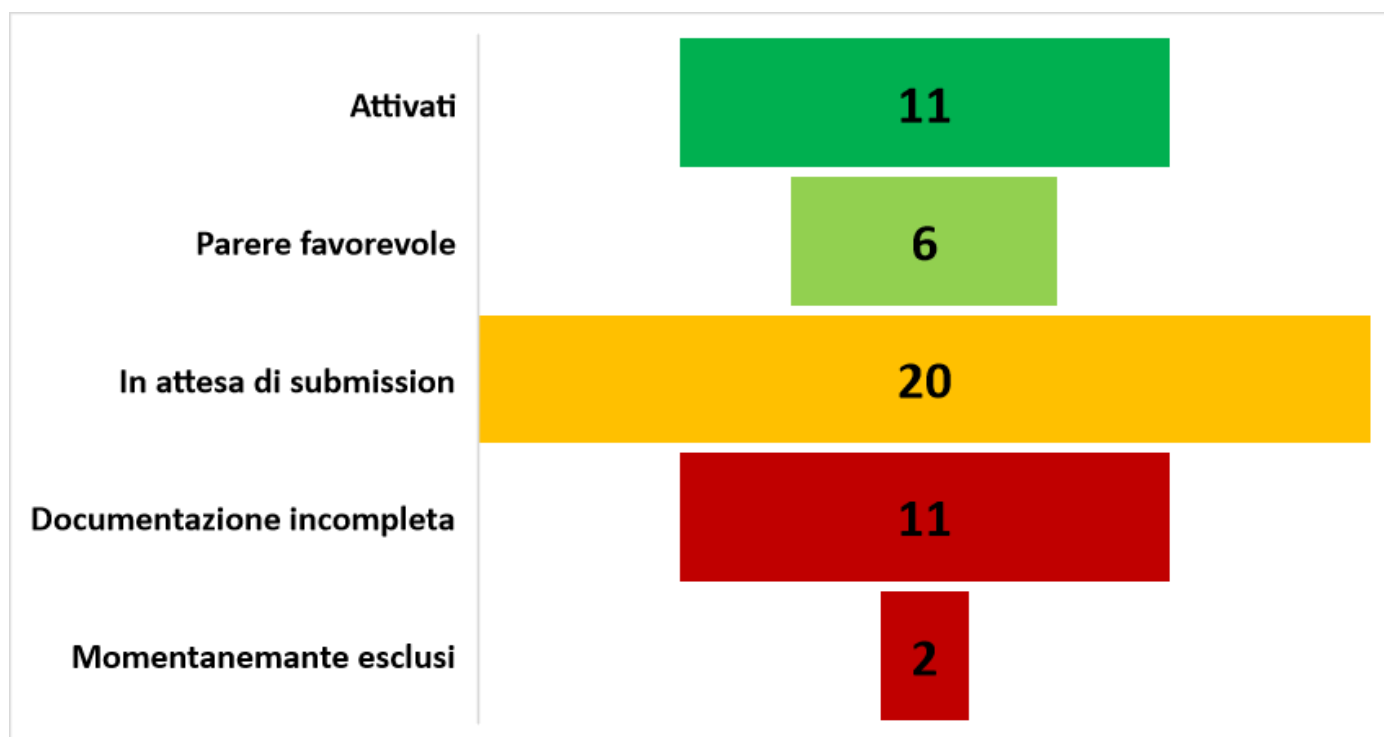
26 PATIENTS ENROLLED



ACTIVE CENTERS WHITH NO PATIENT ENROLLED YET

CENTERS	SIV DATE
Pistoia	27.12.2022
Siena	02.01.2023
Arezzo	08.02.2023
Monzino	24.01.2023
Poliambulanza	27.02.2023

PROGRESS SATUS



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Committee members

Steering committee



Carlo di Mario



Giuseppe Tarantini



Alessio Mattesini



Antonio Bartorelli



Gioel Gabrio Secco



Giovanni Esposito



Francesco Saia



Angelica Rossi



Giulia Masiero



Alaide Chieffo

Data management and monitoring team

**Service For Clinical Trials & Biometrics
Università degli studi di Padova**



Prof. Carlo di Mario

Principal Investigator

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
- Angiographic, IVUS/OCT images must be uploaded in the "procedure file upload" section of the eCRF, before uploading, the images must be anonymized as indicated in the chart
- The follow-ups scheduled at 30 days and 1 year 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)