

Authorship Policy

Prespecified subanalyses

Prespecified substudies





Our Roadmap



Start enrolment August 2019

End enrolment December 2020



- Methodological Manuscript November 2019
- **Italy-Poland-Spain FIRE meeting** EuroPCR (May) 2020
- 700° enrolled patient May 2020 (EuroPCR ???)
- **End primary endpoint follow-up** December 2021
- Main result presentation/publication ESC (August) 2022
- Subanalyses, substudies, extended follow-up 2022-2026



Our Plan and Policy 1 Methodological paper 2. Statistical Analysis Plan publication on the website (with rules for subanalyses) **3.** Policy for authorship (enroll!) and subanalyses (enroll!)









Subanalyses

- with the objective to conduct sub analyses
- - format for subanalysis application
- **3.** Analyses will be performed by our Statistical
 - **Committee (UniFE)**

1 All the Investigators will have access to the database

2. In the next months we will prepare and send you a





Substudies

- 1. treatment and procedures
- They will be conducted in some centers 2.
- 3. CEC
- 4. the website

Prespecified studies requiring the standardization of

They will include several additional analyses by corelab and

Details and protocol of the substudies will be uploaded in





FIRE-HDR **1.** As you well know, the utilization of the Supraflex Cruz stent is highly/strongly suggested in FIRE trial 2. This will allow us to generate data regarding safety and efficacy of this new platform **3.** In particular, we will focus on high dual risk patients (HDR)







High dual risk patients Patients at High: Ischemic (older MI patients with MVD) and Bleeding risk (new ARC-HBR classification)



Urban P, Mehran R, Colleran R, et al Defining high bleeding risk in patients undergoing percutaneous coronary intervention: a consensus document from the Academic Research Consortium for High Bleeding Risk. Eur Heart J. 2019 May 22. pii: ehz372. doi: 10.1093/eurheartj/ehz372.





ARC-HBR criteria

ARC-HBR Major Criteria

- Anticipated use of long-term oral anticoagulation
- Severe or end-stage CKD (eGFR <30 mL/min)</p>
- Hemoglobin <11 g/dL
- Spontaneous bleeding with hospitalization or transfusion (last 6 months or recurrent)
- □ Moderate or severe baseline thrombocytopenia (platelet count <100 X 109/L)
- □ Chronic bleeding diathesis
- Liver cirrhosis with portal hypertension
- □ Active malignancy (excluding non-melanoma skin cancer) within the past 12 months
- Previous spontaneous ICH (at any time)
- Previous traumatic ICH within the past 12 months
- Presence of a brain arteriovenous malformation
- Moderate or severe ischemic stroke within the past 6 months
- Non-deferrable major surgery on DAPT
- Recent major surgery or major trauma within 30 d before PCI

ARC-HBR Minor criteria

- Age ≥75 y
- Moderate CKD (eGFR 30–59 mL/min)
- Hemoglobin 11–12.9 g/dL for men and 11–11.9 g/dL for

- women Spontaneous bleeding requiring hospitalization or transfusion
- within the past 12 months not meeting the major criterion
 - Long-term use of oral NSAIDs or steroids
 - Any ischemic stroke at any time not meeting the major criterion

HBR if 1 major or 2 minor criteria are met





High dual Risk Patients

32% of ACS patients are at Dual High-Risk Age is the main determinant of Dual High-Risk



Mohamed O, IJC 2019



High dual risk patients At least 50% of FIRE trial population is HBR and thus HDR The idea is to test if short DAPT (30 days) is safe and effective in this population

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FIR TRI



FIRE-HDR flow chart



Primary outcome: DOCE at 1-3-5 years

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QFiRe

1. As you well know, QFR will be available in all centers for the enrollment phase 2. This will allow us to generate data regarding efficacy of this new tool **3.** QFR guided vs culprit only revascularization in **FIRE trial patients**







QFR utilization is not mandatory !!! You can use wire-1. based physiology to guide the revascularization in your patients However, the corelab will try to measure QFR in all 2. non culprit vessels.

Remember to acquire projections at 15 f/s 3.











Classy-FIRE Major inclusion criteria: ClearStent availability We will collect procedural and clinical information for patients utilizing ClearStent Propensity matched comparison ClearStent vs conventional PCI optimization





Classy-FIRE flow chart





Cost-effectiveness analysis The aim of the cost-effectiveness analysis is to support the clinical findings, assessing whether the physiology-guided complete revascularization strategy may lead to cost avoidance due to the reduction of adverse event rates





Your subanalyses Please feel free to propose your ideas for additional subanalyses!









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