

Comparison Of Reduced DAPT Followed by P2Y12 Inhibitor Monotherapy With Prasugrel vs stAndard Regimen in STEMI Patients

NCT05491200

Status	RECRUITING
Phase	Phase 4
Sponsor	Research Maatschap Cardiologen Rotterdam Zuid
Enrollment	1,656 participants

Key Eligibility Criteria

Inclusion (13)

- Eligibility at index procedure
- All STEMI patients who are planned to be treated with PCI:
- ST segment elevation myocardial infarction
- Chest discomfort suggestive of cardiac ischemia e20 min at rest with 1 of the following ECG features:
- ST segment elevation e2 contiguous ECG leads

... and 8 more (see full listing online)

Exclusion (15)

- Patients on oral anticoagulation
- Contraindication to P2Y12 inhibitors and/or to Cardioaspirin or to any of the excipients (hypersensitivity, history of any stroke or transient ischemic attack within the last 12 months, active bleeding or haemorrhagic diathesis, fibrin-specific fibrinolytic therapy less than 24 h before randomization, severe hepatic dysfunction (Child-Pugh C), history of asthma induced by the administration of salicylates or substances with a similar action, notably non-steroidal anti-inflammatory medicines, history of gastrointestinal perforation or acute gastrointestinal ulcers, severe cardiac failure (NYHA grade III or IV), combination with methotrexate at doses of 15 mg/week or more).
- Patients who have received P2Y12 inhibitors other than Prasugrel in the ambulance (Ticagrelor or Clopidogrel loading dose) or are already on P2Y12 inhibitors, may be enrolled in the protocol, provided that the Prasugrel loading dose is administered at admission, according to current guidelines recommendations (see section 5.2.2).
- Concomitant oral or i.v. therapy with strong CYP3A inhibitors (e.g., ketoconazole, itraconazole, voriconazole, telithromycin, clarithromycin, nefazodone, ritonavir, saquinavir, nelfinavir, indinavir, atazanavir, grapefruit juice >1L/day), CYP3A substrates with narrow therapeutic indices (e.g., cyclosporine, quinidine), or strong CYP3A inducers (e.g., rifampin), - rifampicin, phenytoin, carbamazepine, dexamethason, phenobarbital
- Platelet count <100.000/L at the time of screening

... and 10 more (see full listing online)

Locations (26 total)

Imelda Bonheiden, Bonheiden, Belgium
AZ St.Jan, Bruges, Belgium
ZOL Genk, Genk, Belgium
... and 23 more locations

<https://clinicaltrials.gov/study/NCT05491200>

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