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Coronary Vasomotor Disorders International Study Group

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# Anti-inflammatory Therapies for Coronary Vasomotor Disorders

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# Anti-inflammatory Therapies for Coronary Vasomotor Disorders: Clinical Trial Design Considerations

## *Talking Points:*

- Introduction
- No recognized effective therapy
- Evidence supporting inflammation in coronary vasomotor disorders
- Question- would addressing inflammation improve symptoms and /or adverse outcomes?
- Approach
- Next steps



# Anti-inflammatory Therapies for Coronary Vasomotor Disorders

- Considerable data show increased levels of blood biomarkers related to inflammation in patients with CMD/other vasomotor ischemia syndromes.
- Limitations of biomarker levels in blood, it remains unclear:
  - whether the marker is causally involved in CMD-ischemic syndrome,
  - whether it is up-regulated in a compensatory manner, or
  - whether it is simply an epiphenomenon (e.g. disabled state resulting from co-morbidities or symptoms).
- Assume it reflects coronary macro and/or microvascular inflammation.



# Anti-inflammatory Therapies for Coronary Vasomotor Disorders

- Target population:
  - Symptoms/signs suggesting IHD
  - Only non obstructive CAD or include those with revascularized obstructive CAD?
  - Definitive diagnosis of microvascular angina-validation of patient symptoms, differentiation from other syndromes with potentially different therapeutic and prognostic implications.
  - Necessary step is transition to routine assessment of CMD using validated techniques.
  - What inclusion criteria for CMD?
    - Multiple studies in CMD suggest increased events in pts with reduced CFR or MPR, using thresholds ranging from 1.5 to 2.5.
    - But <3.0 is clearly evidence of CMD.
  - Initiation of more aggressive risk factor reduction (if benefit is confirmed by future research)
- Assess for effective therapies in microvascular angina pts with CMD.



# Anti-inflammatory Therapies for Coronary Vasomotor Disorders

- Assess for effective therapies specifically in microvascular angina pts with CMD.
  - Study design:
    - Cohort with repeated measures?
    - R, DB, PC?
    - Duration?
    - Outcomes-CFR or angina or others?
    - Potential sample size?
  - Potential sponsors?
- Next steps?