

Colchicine and Spironolactone in Patients With STEMI / SYNERGY Stent Registry (CLEAR-SYNERGY)

ClinicalTrials.gov Identifier: NCT03048825



The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. [Know the risks and potential benefits](#) of clinical studies and talk to your health care provider before participating. Read our [disclaimer](#) for details.

[Recruitment Status](#) ⓘ : Recruiting[First Posted](#) ⓘ : February 9, 2017[Last Update Posted](#) ⓘ : April 19, 2019See [Contacts and Locations](#)**Sponsor:**

Population Health Research Institute

Collaborators:

Canadian Institutes of Health Research (CIHR)

Boston Scientific Corporation

Information provided by (Responsible Party):

Population Health Research Institute

Study Details**Tabular View****No Results Posted**[Disclaimer](#)[? How to Read a Study Record](#)**Study Description**Go to **Brief Summary:**

The CLEAR SYNERGY trial will study the long term effects of treatments following PCI to treat ST elevation myocardial infarction. These treatments address both the culprit artery (PCI with SYNERGY Stent) as well as the non-culprit arteries (randomization to routine colchicine and spironolactone).

Condition or disease ⓘ	Intervention/treatment ⓘ	Phase ⓘ
ST Elevation Myocardial Infarction	Drug: Colchicine	Phase 3
	Drug: Spironolactone	
	Device: SYNERGY Bioabsorbable Polymer Drug-Eluting Stent	
	Drug: Colchicine-Placebo	
	Drug: Spironolactone-Placebo	

Detailed Description:

This is a multicenter, international SYNERGY Stent registry that is embedded within a randomized, blinded, double-dummy, 2x2 factorial design trial of colchicine versus placebo and spironolactone versus placebo in patients with ST-elevation myocardial infarction who have undergone primary percutaneous coronary intervention (PCI).

Study DesignGo to

Study Type  : Interventional (Clinical Trial)
 Estimated Enrollment  : 4000 participants
 Allocation: Randomized
 Intervention Model: Parallel Assignment
 Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)
 Masking Description: double-dummy masking of colchicine and spironolactone in 2x2 factorial
 Primary Purpose: Treatment
 Official Title: A 2x2 Factorial Randomized Controlled Trial of Colchicine and Spironolactone in Patients With ST-elevation Myocardial Infarction (STEMI) / SYNERGY Stent Registry - CLEAR-SYNERGY (OASIS-9)
 Actual Study Start Date  : February 1, 2018
 Estimated Primary Completion Date  : June 30, 2021
 Estimated Study Completion Date  : December 30, 2021

Resource links provided by the National Library of Medicine



[MedlinePlus](#) related topics: [Heart Attack](#)

[Drug Information](#) available for: [Spironolactone](#) [Colchicine](#)

[U.S. FDA Resources](#)

Arms and Interventions

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Arm 	Intervention/treatment 
Experimental: Colchicine + Spironolactone +/- SYNERGY Stent Colchicine 0.5 mg tablet + Spironolactone 25 mg tablet. Trial participants who receive a SYNERGY Bioabsorbable Polymer Drug-Eluting Stent during their index PCI for STEMI will be included in the embedded SYNERGY Stent Registry.	Drug: Colchicine Colchicine 0.5 mg twice daily Drug: Spironolactone Spironolactone 25 mg once daily Device: SYNERGY Bioabsorbable Polymer Drug-Eluting Stent Trial participants who receive a SYNERGY™ Bioabsorbable Polymer Drug-Eluting (everolimus) Stent during their index PCI for STEMI will be included in the SYNERGY Stent Registry.
Experimental: Spironolactone +/- SYNERGY Stent Colchicine-placebo tablet + Spironolactone 25 mg tablet. Trial participants who receive a SYNERGY Bioabsorbable Polymer Drug-Eluting Stent during their index PCI for STEMI will be included in the embedded SYNERGY Stent Registry.	Drug: Spironolactone Spironolactone 25 mg once daily Device: SYNERGY Bioabsorbable Polymer Drug-Eluting Stent Trial participants who receive a SYNERGY™ Bioabsorbable Polymer Drug-Eluting (everolimus) Stent during their index PCI for STEMI will be included in the SYNERGY Stent Registry. Drug: Colchicine-Placebo Matching Colchicine-placebo twice daily
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	Matching Spironolactone-Placebo once daily
Placebo Comparator: Placebo +/- SYNERGY Stent Colchicine-placebo tablet + Spironolactone-placebo tablet. Trial participants who receive a SYNERGY Bioabsorbable Polymer Drug-Eluting Stent during their index PCI for STEMI will be included in the embedded SYNERGY Stent Registry.	Device: SYNERGY Bioabsorbable Polymer Drug-Eluting Stent Trial participants who receive a SYNERGY™ Bioabsorbable Polymer Drug-Eluting (everolimus) Stent during their index PCI for STEMI will be included in the SYNERGY Stent Registry. Drug: Colchicine-Placebo Matching Colchicine-placebo twice daily Drug: Spironolactone-Placebo Matching Spironolactone-Placebo once daily

Outcome Measures

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Primary Outcome Measures :

1. Major Adverse Cardiac Events (MACE) [Time Frame: up to 1 year]

Major Adverse Cardiac Events (MACE) for SYNERGY Stent (defined as the composite of death, recurrent target vessel MI, stroke, or ischemia driven target vessel revascularization) compared to performance goal

2. Composite of cardiovascular death, recurrent myocardial infarction, or stroke [Time Frame: through study completion, an estimated average of 2 years]

The first occurrence of cardiovascular death, recurrent myocardial infarction, or stroke in the colchicine comparison

3. Composite of cardiovascular death or new or worsening heart failure [Time Frame: through study completion, an estimated average of 2 years]

The first occurrence of cardiovascular death or new or worsening heart failure in the spironolactone comparison

Eligibility Criteria

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Information from the National Library of Medicine



Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, [Learn About Clinical Studies](#).

Ages Eligible for Study: 18 Years and older (Adult, Older Adult)

Sexes Eligible for Study: All

Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

1. Patients with STEMI referred for PCI within 12 hours of symptom onset, and have culprit lesion amenable to stenting (after the initial 800 patients received SYNERGY stent [SYNERGY Stent phase], patients will be eligible if referred within 24 hours of symptom onset)

(All patients participating in the drug portion are required to be randomized within 24 hours of index PCI and during initial hospitalization)

2. Written informed consent

Exclusion Criteria:

1. Known allergy or contraindication to everolimus, the SYNERGY stent or any of its components

2. Unable to receive dual antiplatelet therapy
3. Age ≤ 18 years
4. Pregnancy, breastfeeding, or women of childbearing potential who are not using an effective method of contraception
5. Any contraindication or known intolerance to colchicine or spironolactone
6. Requirement for colchicine or spironolactone for another indication
7. Creatinine clearance < 30 mL/min/1.73 m²
8. History of cirrhosis or current severe hepatic disease
9. Systolic blood pressure < 90 mm Hg
10. Serum Potassium > 5.0 meq/L
11. Current or planned use of HIV protease inhibitors, azole antifungals, or macrolide antibiotics
12. Active diarrhea
13. Any medical, geographic, or social factor making study participation impractical or precluding follow-up

Contacts and Locations

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Information from the National Library of Medicine



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Please refer to this study by its ClinicalTrials.gov identifier (NCT number): **NCT03048825**

Contacts

Contact: Christopher Zapallow, MSc 9055274322 ext 40513 clear@phri.ca

Contact: Brandi Meeks, MSc 9055274322 clear@phri.ca

Locations

Canada, Ontario

Hamilton General Hospital

Recruiting

Hamilton, Ontario, Canada, L8L2X2

Contact: CLEAR Investigator 9055274322 clear@phri.ca

Sponsors and Collaborators

Population Health Research Institute

Canadian Institutes of Health Research (CIHR)

Boston Scientific Corporation

Investigators

Principal Investigator: Sanjit S Jolly, MD Population Health Research Institute

More Information

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Responsible Party: Population Health Research Institute

ClinicalTrials.gov Identifier: [NCT03048825](#) [History of Changes](#)

Other Study ID Numbers: CLSYN.1702

OASIS-9 (Other Identifier: Population Health Research Institute)

First Posted: February 9, 2017 [Key Record Dates](#)

Last Update Posted: April 19, 2019

Last Verified: April 2019

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD: Undecided

Studies a U.S. FDA-regulated Drug Product: Yes
Studies a U.S. FDA-regulated Device Product: Yes
Device Product Not Approved or Cleared by U.S. FDA: No
Pediatric Postmarket Surveillance of a Device Product: No
Product Manufactured in and Exported from the U.S.: No

Additional relevant MeSH terms:

Infarction	Hormone Antagonists
Myocardial Infarction	Hormones, Hormone Substitutes, and Hormone Antagonists
ST Elevation Myocardial Infarction	Physiological Effects of Drugs
Ischemia	Diuretics, Potassium Sparing
Pathologic Processes	Diuretics
Necrosis	Natriuretic Agents
Myocardial Ischemia	Gout Suppressants
Heart Diseases	Antirheumatic Agents
Cardiovascular Diseases	Tubulin Modulators
Vascular Diseases	Antimitotic Agents
Spironolactone	Mitosis Modulators
Colchicine	Molecular Mechanisms of Pharmacological Action
Mineralocorticoid Receptor Antagonists	Antineoplastic Agents

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