ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: February 8, 2018

ClinicalTrials.gov ID: NCT03229993

## Study Identification

| | |
|---|---|
| Unique Protocol ID: | OCT-20170723 |
| Brief Title: | OCT in Borderline Coronary Artery Lesions |
| Official Title: | The Safety and Efficacy of OCT in the Evaluation and Treatment of Angiographically Borderline Coronary Artery Lesions |
| Secondary IDs: | |

## Study Status

| | |
|---|---|
| Record Verification: | July 2017 |
| Overall Status: | Recruiting |
| Study Start: | December 31, 2017 [Actual] |
| Primary Completion: | January 31, 2018 [Actual] |
| Study Completion: | December 31, 2018 [Anticipated] |

## Sponsor/Collaborators

| | |
|---|---|
| Sponsor: | The First Affiliated Hospital with Nanjing Medical University |
| Responsible Party: | Sponsor |
| Collaborators: | |

## Oversight

| | |
|---|---|
| U.S. FDA-regulated Drug: | No |
| U.S. FDA-regulated Device: | No |
| U.S. FDA IND/IDE: | No |
| Human Subjects Review: | Board Status: Approved<br>Approval Number: 2017-SR-328<br>Board Name: Ethics committee of Jiangsu Provincial People's Hospital<br>Board Affiliation: the First Affiliated Hospital of Nanjing Medical University<br>Phone: 86 02583718836<br>Email:<br>Address:<br><br>Guangzhou Road 300, Nanjing, China |
| Data Monitoring: | |

## Study Description

**Brief Summary:** To find out the safety and efficacy of Optical Coherence Tomography (OCT) in the evaluation and treatment of angiographically borderline coronary artery lesions in a Chinese population, and to compare the effectiveness of OCT versus SPECT in treating such subjects. All the participants included in the study will be those that are found to have borderline coronary artery lesions on coronary angiography, in whom the investigators feel that OCT will be useful to assess whether PCI will be of benefit to the treatment of the lesion pathology, or whether optimal medical therapy is the most appropriate treatment modality. Those participants who declined OCT will be offered SPECT as an alternative method to assess and treat the borderline coronary artery stenosis.

It is estimated that OCT guided “PCI or not” has a non-inferiority to SPECT's in the borderline coronary artery stenosis.

**Detailed Description:**

## Conditions

**Conditions:** Optical Coherence Tomography (OCT)
Percutaneous Coronary Intervention (PCI)
Single-Photon Emission Computed Tomography (SPECT)
Coronary Angiography (CAG)
Borderline Coronary Artery Lesions

**Keywords:**

## Study Design

**Study Type:** Interventional

**Primary Purpose:** Treatment

**Study Phase:** N/A

**Interventional Study Model:** Parallel Assignment

**Number of Arms:** 4

**Masking:** None (Open Label)

**Allocation:** Non-Randomized

**Enrollment:** 120 [Anticipated]

## Arms and Interventions

| Arms | Assigned Interventions |
|---|---|
| Experimental: OCT guided PCI | Diagnostic Test: OCT<br>OCT is used to assess whether PCI will be of benefit to the treatment of the borderline coronary artery lesions |
| Experimental: OCT guided medicine | Diagnostic Test: OCT<br>OCT is used to assess whether PCI will be of benefit to the treatment of the borderline coronary artery lesions |
| No Intervention: SPECT guided PCI | |
| No Intervention: SPECT guided medicine | |

## Outcome Measures

Primary Outcome Measure:

1. MACEs
   The incidence of major adverse cardiac events (MACEs) including death, myocardial infarction, and stent thrombosis.

   [Time Frame: 12 months]
2. TLR
   The incidence of target lesion revascularization (TLR)

   [Time Frame: 12 months]

Secondary Outcome Measure:

3. Rehospitalization
   The incidence of rehospitalization due to cardiac events

   [Time Frame: 12 months]
4. Recurrent angina
   The incidence of recurrent angina

   [Time Frame: 12 months]

## Eligibility

| | |
|---|---|
| Minimum Age: | |
| Maximum Age: | |
| Sex: | All |
| Gender Based: | No |
| Accepts Healthy Volunteers: | No |
| Criteria: | Inclusion Criteria: |

- The inclusion criteria for this study will be only those participants in whom diagnostic coronary angiography revealed borderline coronary artery lesion. These participants will undergo the OCT procedure, or alternatively ECT.

Exclusion Criteria:

- Exclusion criteria will be those participants with previous cardiogenic shock, stroke, renal dysfunction, and acute or chronic total occlusion coronary lesions.

## Contacts/Locations

| | |
|---|---|
| Central Contact Person: | Liansheng Wang, Doctor<br>Telephone: 86 25 68303125<br>Email: drlswang@njmu.edu.cn |
| Central Contact Backup: | Haoyu Meng, Doctor<br>Telephone: 86 25 68303126<br>Email: haoyu_meng@163.com |
| Study Officials: | |
| Locations: | China, Jiangsu<br>First Affiliated Hospital of Nanjing Medical University |

[Recruiting]
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## IPDSharing

Plan to Share IPD: Undecided

## References

Citations:

Links:

Available IPD/Information: