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Clinical Trial Design

Rationale and design of the PREDICT (Plaque Registration and Evaluation Detected In Computed Tomography) registry

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ABSTRACT

Background: At least two-thirds of cases of acute coronary syndrome are caused by disruption of an atherosclerotic plaque. The natural history of individual plaques is unknown and needs to be established.

Objectives: The Plaque Registration and Evaluation Detected In Computed Tomography (PREDICT) registry is a prospective, multicenter, longitudinal, observational registry. This registry was designed to examine the relationships among coronary CT angiography (CTA) findings and clinical findings, mortality, and morbidity. The relationships among progression of coronary atherosclerosis, including changes in plaque characteristics on coronary CTA, and serum lipid levels and modification of coronary risk factors will also be evaluated.

Methods: From October 2009 to December 2012, 3015 patients who underwent coronary CTA in 29 centers in Japan were enrolled. These patients were followed for 2 years. The primary end points were considered as all-cause mortality and major cardiac events, including cardiac death, nonfatal myocardial infarction, and unstable angina that required hospitalization. The secondary end points were heart failure that required administration of diuretics, target vessel revascularization, cerebral infarction, peripheral arterial disease, and invasive coronary angiography. Blood pressure, serum lipid, and C-reactive protein levels and all cardiovascular events were recorded at 1 and 2 years. If the initial coronary CTA showed any stenosis or plaques, follow-up coronary CTA was scheduled at 2 years to determine changes in coronary lesions, including changes in plaque characteristics.

Conclusion: Analysis of the PREDICT registry data will clarify the relationships between coronary CTA findings and cardiovascular mortality and morbidity in a collaborative

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multicenter fashion. This trial is registered at www.clinicaltrials.gov as NCT 00991835.

1. Introduction

Coronary CT angiography (CTA) with the use of 64 or more detector rows is a recently introduced noninvasive method of evaluating coronary artery disease (CAD) with high diagnostic accuracy for the detection or exclusion of obstructive CAD.[1,2] Coronary CTA findings about the presence and extent of CAD were reported to be strong predictors of cardiovascular events.[3,4] Coronary CTA is also expected to be a useful tool for evaluating plaque characteristics because it can visualize the structure of coronary vessels and morphologic features of coronary plaques.[5,6] Acute coronary syndrome is mainly attributable to the acute rupture of vulnerable plaques, characterized by positive remodeling with lipid-rich, thin fibroatheroma and subsequent thrombus formation.[7,8] Several studies that used intravascular ultrasonography have reported that coronary positive vessel remodeling (PR), low-attenuation plaques (LAPs), and spotty calcification are associated with plaque vulnerability.[9–11] Therefore, it is crucial to detect and stabilize rupture-prone plaques non-invasively to prevent cardiovascular events. The characteristics of coronary plaques are hypothesized to predict future coronary events.

The Plaque Registration and Evaluation Detected In Computed Tomography (PREDICT) registry was developed to provide a database of coronary CTA findings that could be used to identify risk factors for cardiac events. This report describes the rationale and design of the PREDICT registry.

2. Methods

2.1. Overall study design

The PREDICT registry is a prospective, multicenter, observational registry designed to examine the relationships among coronary CTA findings and clinical findings, mortality, and specific events in patients with clinically suspected and proven CAD (Fig. 1). This registry uses a novel collaborative design that merges similar prospectively enrolled cohorts from 29 hospitals in Japan. This study is registered at www.clinicaltrials.gov as NCT 00991835.

2.2. Study objectives

The primary objective of the PREDICT registry is to examine the relationships among coronary CTA findings and demographic data, clinical data, and events caused by CAD in the 3015 enrolled patients. Specifically, the registry data will be analyzed to identify specific coronary CTA findings that can predict cardiovascular events during the next 2 years and to clarify the associations between plaque characterization on coronary CTA and culprit lesions at the time of presentation of acute coronary syndrome.

The secondary objectives of the PREDICT registry include the following: to examine the relationships among coronary CTA findings and clinical risk factors and therapeutic interventions for CAD and to evaluate relationships among

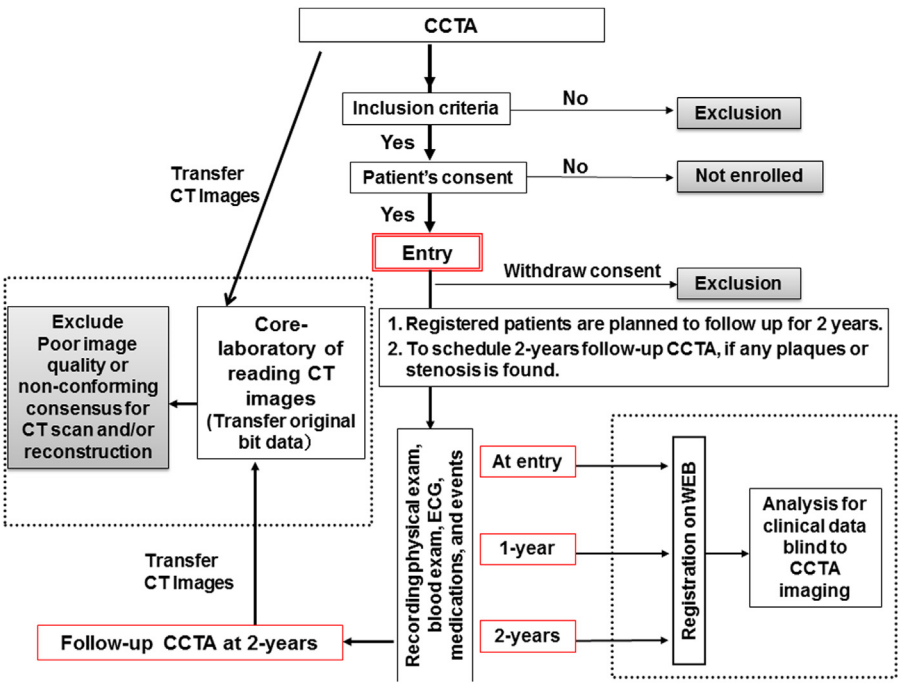

Fig. 1 – Chart of study design. CTA, CT angiography; ECG, electrocardiogram.