Candesartan Antihypertensive Survival Evaluation in Japan (CASE-J) Trial of Cardiovascular Events in High-Risk Hypertensive Patients

The recruitment status of this study is unknown. The completion date has passed and the status has not been verified in more than two years.

Verified April 2005 by The Japanese Society of Hypertension.
Recruitment status was: Active, not recruiting

Sponsor:
The Japanese Society of Hypertension

Information provided by:
The Japanese Society of Hypertension

ClinicalTrials.gov Identifier:
NCT00125463

First received: July 29, 2005
Last updated: August 8, 2005
Last verified: April 2005

Purpose

The purpose of this study is to compare an angiotensin II receptor antagonist (candesartan cilexetil—Blopress®) and a calcium channel blocker (amlodipine besilate—Norvasc®/Amlodin®) in terms of the incidence of cardiovascular events among high-risk hypertensive patients.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
<th>Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypertension</td>
<td>Drug: Candesartan cilexetil</td>
<td>Phase 3</td>
</tr>
<tr>
<td>Cardiovascular Diseases</td>
<td></td>
<td></td>
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</tbody>
</table>
**Study Type:** Interventional  
**Study Design:** Allocation: Randomized  
Intervention Model: Parallel Assignment  
Masking: Open Label  
Primary Purpose: Treatment  

**Official Title:** Candesartan Antihypertensive Survival Evaluation in Japan (CASE-J) Trial of Cardiovascular Events in High-Risk Hypertensive Patients  

**Resource links provided by NLM:**  
MedlinePlus related topics: Blood Pressure Medicines  
Drug Information available for: Candesartan, Candesartan cilexetil  
U.S. FDA Resources  

**Further study details as provided by The Japanese Society of Hypertension:**  

**Primary Outcome Measures:**  
- Sudden death: death of endogenous origin within 24 hours after acute onset  
- Cerebrovascular events: new occurrence or recurrence of a stroke or transient ischemic attack  
- Cardiac events: new occurrence, aggravation, or recurrence of heart failure, angina pectoris, or acute myocardial infarction  
- Renal dysfunction: serum creatinine ≥4.0 mg/dl, end stage renal disease, doubling of serum creatinine (however, creatinine ≤2.0 mg/dl is not regarded as an event)  
- Vascular events: new occurrence or aggravation of dissecting aneurysm of aorta, arteriosclerotic occlusion of peripheral artery  

**Secondary Outcome Measures:**  
- All deaths  
- Involution of left ventricular hypertrophy (LVMI)  
- Proportion of the subjects who withdrew from the allocated treatment  

**Estimated Enrollment:** 3200  
**Study Start Date:** September 2001  
**Estimated Study Completion Date:** December 2005  

**Detailed Description:**  
Hypertension continues to be a major public health issue in the world. To combat this problem, many antihypertensive drugs have been developed and proven effective at controlling blood pressure in the last half century. In recent decades, antihypertensive drugs have been shown to have cardiovascular benefits beyond the reduction of blood pressure, and the focus has shifted to clarification of these effects. Angiotensin II receptor antagonists and calcium channel blockers are
the most widely used antihypertensive drugs in Japan. However, these two classes of drugs have not yet been compared with respect to their efficacy for treating cardiovascular events.

Comparison: Response-dependent dose titration and blinded assessment of endpoints in high risk hypertensive patients treated with either an angiotensin II receptor antagonist (candesartan cilexetil) compared to a third-generation calcium channel blocker (amlodipine besilate).

► Eligibility

Ages Eligible for Study: 25 Years to 85 Years (Adult, Senior)
Sexes Eligible for Study: All
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Systolic blood pressure (SBP) ≥140 mmHg in those <70 years old or ≥160 mmHg in those ≥70 years old or diastolic blood pressure (DBP) ≥90 mmHg in a sitting position on two consecutive measurements at clinic
- At least one of the following risk factors:
  - SBP ≥180 mmHg or DBP ≥110 mmHg on two consecutive visits;
  - Type 2 diabetes (fasting blood glucose ≥126 mg/dl, casual blood glucose ≥200 mg/dl, HbA1c ≥6.5%, 2 hours blood glucose on 75 g oral glucose tolerance test [OGTT] ≥200 mg/dl, or current treatment with hypoglycemic agent);
  - History of cerebral hemorrhage, cerebral infarction, or transient ischemic attack until 6 months prior to the screening;
  - Thickness of the posterior wall of left ventricle or thickness of the wall of interventricular septum ≥12 mm on echocardiography or Sv1 + Rv5 ≥35 mm on electrocardiography, angina pectoris, and a past history (≥6 months before giving informed consent) of myocardial infarction;
  - Proteinuria ≥1 or renal impairment (serum creatinine ≥1.3 mg/dl) within 3 months at the time of giving informed consent;
  - Arteriosclerotic peripheral arterial obstruction (Fontaine class ≥2); *Clinical diagnosis of Alzheimer’s disease.

Exclusion Criteria:

- SBP ≥200 mmHg or DBP ≥120 mmHg in a sitting position
- Type I diabetes mellitus
- History of myocardial infarction or cerebrovascular accidents within 6 months prior to the screening
- Percutaneous transluminal coronary angioplasty (PTCA) or coronary artery bypass grafting (CABG) done within 6 months of screening or scheduled
- Current treatment for congestive cardiac failure (New York Heart Association [NYHA] functional class II or severer) or ejection fraction <40%
- Coronary artery disease requiring αβ blocker or calcium channel blocker
- Atrial fibrillation or atrial flutter
- Renal dysfunction (serum creatinine ≥3 mg/dl)
• Hepatic dysfunction (AST and/or ALT ≥100 IU/l)
• A history of malignant tumor within 5 years of enrollment or suspected
• Contraindication for candesartan cilexetil or amlodipine besilate
• Pregnancy, possible pregnancy, or plan to conceive a child within 5 years of enrollment
• Not suited to the clinical trial as judged by a collaborating physician
• Inability to give informed consent

Contacts and Locations

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, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT00125463

Locations

Japan

Kyoto University
Kyoto, Yoshidakonoe-cho, Sakyo-ku, Kyoto, Japan, 606-8501

Sponsors and Collaborators

The Japanese Society of Hypertension

Investigators

Principal Investigator: Takao Saruta, M.D. Keio University

More Information

Publications:


Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Other Study ID Numbers: JSH-00001
Study First Received: July 29, 2005
Last Updated: August 8, 2005

Keywords provided by The Japanese Society of Hypertension:
Hypertension
clinical trial
Candesartan Antihypertensive Survival Evaluation in Japan trial
candesartan cilexetil
amlodipine besilate

Additional relevant MeSH terms:
Hypertension
Cardiovascular Diseases
Vascular Diseases
Candesartan
Candesartan cilexetil

ClinicalTrials.gov processed this record on July 31, 2017