

Main

Note: This record shows only 22 elements of the WHO Trial Registration Data Set. To view changes that have been made to the source record, or for additional information about this trial, click on the URL below to go to the source record in the primary register.

Register: JPRN
Last refreshed on: 6 April 2022
Main ID: JPRN-UMIN000021154
Date of registration: 23/02/2016
Prospective Registration: Yes
Primary sponsor: Tokorozawa Heart Center
Public title: Prospective, randomized, open-label, clinical trial comparing the effects of hydrogen tablet and placebo on blood pressure, endothelial function and makers for cardiovascular diseases
Scientific title: Prospective, randomized, open-label, clinical trial comparing the effects of hydrogen tablet and placebo on blood pressure, endothelial function and makers for cardiovascular diseases - Effects of hydrogen tablet on blood pressure and endothelial function
Date of first enrolment: 2016/02/23
Target sample size: 34
Recruitment status: Recruiting
URL: https://center6.umin.ac.jp/cgi-open-bin/ctr_e/ctr_view.cgi?recptno=R000024401
Study type: Interventional
Study design: Cross-over Randomized
Phase: Not selected

Countries of recruitment

Japan

Contacts

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Key inclusion & exclusion criteria

Inclusion criteria:

Exclusion criteria: 1) Poor-controlled hypertension (DBP>110)

2) Poor-controlled diabetes (HbA1c>8.0 %)

3) Secondary hypertension

4) History of stroke, acute coronary syndrome or any cardiovascular diseases needed for inpatient-treatments within 6 months

5) Either level of aspartate aminotransaminase or alanine aminotransferase exceeds three-fold of the normal limits.

6) End stage renal disease

7) Symptomatic (NYHA III or IV) congestive heart failure

8) Malignancies or other diseases with poor prognosis

9) Subjects whose doctor in charge do not agree to join the trial

Age minimum: 20years-old

Age maximum: 80years-old

Gender: Male and Female

Health Condition(s) or Problem(s) studied

Hypertension

Intervention(s)

hydrogen tablet 2tab/day for 12 weeks

>

placebo 2tab/day for 12 weeks

>

placebo 2tab/day for 12 weeks

>

hydrogen tablet 2tab/day for 12 weeks

Primary Outcome(s)

Blood pressure (On visit/Home monitoring/24 hr ambulatory)

Flow-mediated vasodilation in forearm

12 weeks after administration

Secondary Outcome(s)

Markers indicating obesity (e.g. adiponectin), inflammation (high sensitive CRP), oxidative stress (8-OHdG/MDA-LDL), early-staged kidney diseases (microalbuminuria)

12 weeks after administration

Secondary ID(s)

Source(s) of Monetary Support

Foundation for Promotion of Defense Medicine

Secondary Sponsor(s)

Ethics review

Status: YES

Approval date:

Contact:

Results

Results available:

Date Posted:

Date Completed:

URL:

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