

Adherence to triple combination therapy in hypertensive patients

Submission date 01/03/2016	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 03/03/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 25/04/2023	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Hypertension, also known as high blood pressure, is a very common, long term condition. The heart is responsible for pumping blood around the body to deliver oxygen-rich blood. In order to do this a certain amount of pressure is needed in the blood vessels, but if this pressure is too high, then it puts a great strain on the arteries and heart. Many people with high blood pressure are unaware of it, as it rarely causes any noticeable symptoms. If left untreated however, it dramatically increases the risk of heart disease, kidney disease and stroke, earning it the nickname of the “silent killer”. There are a wide range of medications used to treat high blood pressure, which can be very effective. It has been found however that many patients do not take their medications properly (either by missing doses or taking them sporadically), meaning that they do not receive all of the benefits that their medications are meant to provide. Many blood pressure medications are used in combination with one another and this study will be looking at three: Olmesartan, Amlodipine and Hydrochlorothiazide. The aim of this study is to find out whether patients are more likely to take their combination antihypertensive treatment properly if it is in the form of a single pill or as two pills.

Who can participate?

Adults with hypertension who have been treated with a combination of medications for at least four weeks.

What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group are given a single pill to take, which contains Olmesartan 20 mg, Amlodipine 5 mg and Hydrochlorothiazide 12.5 mg, every day for 12 weeks. Those in the second group are given two pills to take every day, one pill containing Olmesartan 20 mg and Hydrochlorothiazide 12.5 mg and the other containing Amlodipine 5 mg, for 12 weeks. Participants in both groups are monitored for the entire 12 week study period in order to find out how well the participants in each group are taking their medication and whether they are taking it correctly. The difference in each groups' blood pressure is also measured at the clinic and at home, so that the two results can be compared.

What are the possible benefits and risks of participating?

Not provided at time of registration.

Where is the study run from?

Samsung Medical Center (lead centre) and 16 other medical centres in South Korea.

When is the study starting and how long is it expected to run for?

February 2016 to February 2017

Who is funding the study?

Daiichi-Sankyo (Japan)

Who is the main contact?

Dr Jidong Sung

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Contact information

Type(s)

Scientific

Contact name

Dr Jidong Sung

Contact details

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Additional identifiers

Protocol serial number

20151026

Study information

Scientific Title

Adherence measured by Medication event monitoring system in TPipe Antihypertensive Combination: single- versus two-pill regimen

Acronym

AMTRAC

Study objectives

Triple-component single-pill combination has advantage in adherence over equivalent 2-pill combination therapy.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Institutional Review Board, Samsung Medical Hospital, Seoul, Republic of Korea, ref: 2015-11-109

Study design

Multi-centre open-label randomised parallel trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Hypertension

Interventions

Eligible patients are randomized either to the single-pill arm or the two-pill arm, for a total of 12 weeks.

Single-pill arm: SevicarHCT (Olmesartan 20 mg + Amlodipine 5 mg + Hydrochlorothiazide 12.5 mg)

Two-pill arm: Olmetec plus (Olmesartan 20 mg + Hydrochlorothiazide 12.5 mg) and Amlodipine 5 mg

Medications are dispensed in MEMS (MEMS V TrackCap (Aardex, Ltd., Zug, Switzerland), one container for one pill, (thus one container for one-pill group and two containers for two-pill group) and monitored for entire study period and the data is transferred to computer and analyzed by Powerview V (Aardex, Ltd., Zug, Switzerland).

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

1. Olmesartan 2. Amlodipine 3. Hydrochlorothiazide

Primary outcome(s)

Difference of percentage of dose taken (PDT) between 1-pill therapy and 2-pill therapy, measured by medication event monitoring system at 12 weeks.

Key secondary outcome(s)

1. Percentage of days with prescribed dose taken correctly (PDTc) between 1-pill therapy and 2-pill therapy is determined using the medication event monitoring system at 12 weeks
2. Difference in proportion of PDT and PDTc over 80% is measured using the medication event

monitoring system at 12 weeks

3. Difference in mean clinic and home systolic blood pressure between 1- and 2-pill therapy is determined at 12 weeks

Completion date

31/12/2018

Eligibility

Key inclusion criteria

1. Hypertensive patients whose clinic BP (defined below) is systolic > 140 mmHg or diastolic > 90 mmHg, and has been on dual-component therapy for at least 4 weeks with one of the following combination either in SPC or free-equivalent combination in a dose equivalent dose to olmesartan 20 mg or amlodipine 5 mg or hydrochlorothiazide 12.5 mg/day:
 - 1.1. Angiotensin receptor blocker(ARB) + Calcium channel blocker(CCB)
 - 1.2. ARB + thiazide diuretics
 - 1.3. CCB + thiazide diuretics
2. Patients who provide informed consent to join the study
3. Aged 18 years or over

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

145

Key exclusion criteria

1. Severe HTN (baseline clinic SBP > 180 mmHg or DBP > 110 mmHg)
2. Suspicious of secondary HTN or any other severe target organ damage or hypertensive emergency necessitating urgent BP control
3. Past history of intolerance or existing contraindication to either CCB or ARB or thiazide diuretics
4. Medical conditions which are likely to result in regimen change such as recent (within 6 months) major cardiovascular events.
5. Cases with severe comorbidities which is considered to be inappropriate for enrollment by investigators, including (but not confined to) severe hepatic or renal insufficiency, dementia with significant problem in keeping regular medication, etc.
6. Pregnancy or planned pregnancy

Date of first enrolment

15/03/2016

Date of final enrolment

31/08/2018

Locations

Countries of recruitment

Korea, South

Study participating centre**Samsung Medical Center**

81, Irwon-ro, Gangnam-gu

Seoul

Korea, South

06351

Study participating centre**Kangbuk Samsung Hospital**

29, Saemunan-ro, Jongno-gu

Seoul

Korea, South

03181

Study participating centre**Kangwon National University Hospital**

156, Baengnyeong-ro

Chuncheon-si

Korea, South

24289

Study participating centre**Kosin University Gospel Hospital**

262, Gamcheon-ro, Seo-gu

Busan

Korea, South

49267

Study participating centre

Catholic Kwandong University International St. Mary's Hospital
25, Simgok-ro 100beon-gil, Seo-gu
Incheon
Korea, South
22711

Study participating centre
National Cancer Center
323, Ilsan-ro, Ilsandong-gu
Goyang-si
Korea, South
10408

Study participating centre
Dankook University Hospital
201, Manghyang-ro, Dongnam-gu
Cheonan-si
Korea, South
31116

Study participating centre
Samyook Medical Center
82, Mangu-ro, Dongdaemun-gu
Seoul
Korea, South
02500

Study participating centre
Sejong Hospital
28, Hohyeon-ro 489beon-gil, Sosa-gu
Bucheon-si
Korea, South
14754

Study participating centre
Inje University Ilsan Paik Hospital
170, Juhwa-ro, Ilsanseo-gu
Goyang-si
Korea, South
10380

Study participating centre
Inje University Haeundae Paik Hospital
875, Haeun-daero, Haeundae-gu
Busan
Korea, South
48108

Study participating centre
Chung-Ang University Hospital
102, Heukseok-ro, Dongjak-gu
Seoul
Korea, South
06973

Study participating centre
Samsung Changwon Hospital
158, Paryong-ro, MasanHoewon-gu
Changwon-si
Korea, South
51353

Study participating centre
Chungnam National University Hospital
282, Munhwa-ro, Jung-gu
Daejeon
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35015

Study participating centre
Kepeco Medical Center
308, Uicheon-ro, Dobong-gu
Seoul
Korea, South
01450

Study participating centre
Eulji University Hospital
95, Dunsanse-ro, Seo-gu
Daejeon

Korea, South
35233

Study participating centre

VHS Medical Center

53, Jinhwangdo-ro 61-gil, Gangdong-gu
Seoul
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05368

Sponsor information

Organisation

Sungkyunkwan University School of Medicine

ROR

<https://ror.org/04q78tk20>

Funder(s)

Funder type

Industry

Funder Name

Daiichi-Sankyo

Alternative Name(s)

Daiichi Sankyo Company, Limited, Daiichi Sankyo Co., Ltd.

Funding Body Type

Private sector organisation

Funding Body Subtype

For-profit companies (industry)

Location

Japan

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		13/02/2021	25/04/2023	Yes	No
Basic results		02/03/2020	02/03/2020	No	No