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Adherence to triple combination therapy in hypertensive patients

Submission date 01/03/2016	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 03/03/2016	**Overall study status** Completed	
Last Edited 25/04/2023	**Condition category** Circulatory System	

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?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
20151026

Study information

Scientific Title
Adherence measured by Medication event monitoring system in TPiple 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

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
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

Overall study start date
01/02/2016

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
300

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
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Seoul
Korea, South
02500

Study participating centre

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

Study participating centre
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170, Juhwa-ro, Ilsanseo-gu
Goyang-si
Korea, South
10380

Study participating centre
Inje University Haeundae Paik Hospital
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48108

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102, Heukseok-ro, Dongjak-gu
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06973

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

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

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

Study participating centre
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Korea, South
35233

Study participating centre
VHS Medical Center
53, Jinhwangdo-ro 61-gil, Gangdong-gu
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Korea, South
05368

Sponsor information

Organisation
Sungkyunkwan University School of Medicine

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81 Ilwon-ro, Kangnam-gu
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Korea, South
06351

Sponsor type
University/education

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

Publication and dissemination plan
Not provided at time of registration.

Intention to publish date
31/12/2019

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?
Basic results		02/03/2020	02/03/2020	No	No
Results article		13/02/2021	25/04/2023	Yes	No