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Evaluation of controlling high blood pressure using a combined amlodipine and perindopril arginine approach in Morocco

Submission date 26/03/2024	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 05/04/2024	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 04/04/2024	**Condition category** Circulatory System	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
The SYNERGIA study was conducted in private healthcare facilities in Morocco to assess how effective a combination of two medications, amlodipine and perindopril arginine, is in managing high blood pressure (hypertension).

Who can participate?
Patients aged 18 years or older who are hypertensive and previously treated with amlodipine monotherapy, uncontrolled and for whom the treating physician decides to add perindopril arginine.

What does the study involve?
The research focused on adults who were already taking amlodipine for their high blood pressure but were still not seeing improvement. In response, their doctors decided to add perindopril arginine to their treatment plan. The main goal of the study is to see how effective this combination of medications (amlodipine and perindopril arginine) is for patients who are still struggling with high blood pressure despite taking amlodipine alone. The study lasted for 90 days.

This study, which involved 1600 patients from different medical centers across Morocco, looked at vital signs like blood pressure (both systolic and diastolic) and heart rate at three points: 30, 60, and 90 days into the study.

What are the possible benefits and risks of participating?
The combination of amlodipine and perindopril arginine have been proven in studies conducted in several countries showing the benefits of a fixed combination amlodipine-perindopril in lowering blood pressure, heart rate, improving medication adherence and safety, and reducing adverse events.

Where is the study run from?
SERVIER (Morocco)

When is the study starting and how long is it expected to run for?
March 2023 to March 2024

Who is funding the study?
SERVIER (Morocco)

Who is the main contact?
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Contact information

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Public, Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IC4-05985-014-MAR

Study information

Scientific Title
Effectiveness of hypertension management with an amlodipine and perindopril arginine-based strategy in Morocco

Acronym
SYNERGIA-MOROCCO

Study objectives
Hypertensive patients, initially uncontrolled on amlodipine monotherapy, whose treating physician adds perindopril arginine as adjunctive therapy to achieve hypertension control, and then switches to a fixed-dose combination of amlodipine-perindopril arginine, exhibit effective hypertension management.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 23/10/2023, Committee for Biomedical Research (CERB) of The Faculty of Medicine and Pharmacy- Rabat (Faculty of Medicine and Pharmacy- Rabat, Rabat, 10000, Morocco; +212 537 77 35 60; guedirak@yahoo.fr), ref: 48/23

Study design
Prospective multicenter observational study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Other

Study type(s)
Efficacy

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Hypertension

Interventions
This is an observational study that involves the observation of 1600 hypertensive patients in Morocco over a span of 90 days. Physicians will adapt medication (amlodipine-perindopril arginine fixed combination) dosages as required to regulate blood pressure levels, while monitoring vital signs such as blood pressure and heart rate at 30, 60 and 90 days. Additionally, other factors such as medical history will be taken into consideration during the evaluation process.

Intervention Type
Drug

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
amlodipine-perindopril arginine fixed combination

Primary outcome measure
Systolic blood pressure (SBP) and diastolic blood pressure (DBP) in the supine position at baseline, 30, 60 and 90 days

Secondary outcome measures
1. Supine SBP and DBP between the start of the study and the start of fixed therapy measured using a sphygmomanometer
2. Reported side effects between the start of the amlodipine-perindopril arginine fixed combination and the end of the study measured using patient records

Overall study start date
01/03/2023

Completion date
15/03/2024

Eligibility

Key inclusion criteria
1. Men or women aged ≥18 years who document informed consent.
2. Hypertensive patients previously treated with amlodipine monotherapy, uncontrolled and for whom the treating physician decides to add perindopril arginine.

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
1600

Total final enrolment
1614

Key exclusion criteria
1. Age < 18 years
2. Pregnancy, breastfeeding or possibility of becoming pregnant during the study
3. Current participation in another randomized study or within the previous 3 months
4. Known symptomatic orthostatic hypotension
5. Known hyperkalemia or hypokalemia
6. History of arterial hypertension known to be resistant to the free combination or in a single tablet with perindopril and calcium channel blockers or contraindications to treatment with perindopril or amlodipine
7. Known secondary hypertension or complicated hypertension
8. Known renal insufficiency: patients with a creatinine clearance value classifying them as moderate or severe renal insufficiency according to the national or international classification of chronic renal insufficiency or bilateral stenosis of the renal artery or stenosis at solitary kidney or history of gout
9. Known complicated liver disease
10. Chronic pancreatitis
11. History of heart disease: cardiogenic shock, myocardial infarction within 6 months prior to selection, hemodynamically unstable heart failure after acute myocardial infarction, coronary revascularization within 6 months previous congestive heart failure within 6 months prior to selection or history of congestive heart failure with NYHA grade III or IV, severe aortic or mitral valve stenosis or hypertrophic obstructive cardiomyopathy
12. Recent ventricular rhythm disorders
13. History of cerebrovascular disease
14. Hypersensitivity to active substances, other sulfonamides, dihydropyridine derivatives and any ACE inhibitors
15. History of angioedema (angioedema) associated with previous treatment with an ACE inhibitor
16. Hereditary/idiopathic angioedema
17. Hepatic encephalopathy
18. Concomitant use of the fixed combination of perindopril and amlodipine with products containing aliskiren in patients with diabetes mellitus or renal insufficiency (GFR < 60 ml/min/1. 73 m^2)
19. Any other contraindication according to the SPC (Summary of Product Characteristics) of the medicinal product.

Date of first enrolment
30/10/2023

Date of final enrolment
13/12/2023

Locations

Countries of recruitment
Morocco

Study participating centre
Private Cardiologists Centers in Morocco
Agadir, Ameziane, Beni Mellal, Berrechid, Bir jdid, Casablanca, Dar Bouazza, El jadida, Fes, Khemisset, Marrakech, Meknes, Oujda, Oulad Teima, Rabat, Safi, Salé, Tétouan, Tanger, Taroudant, Temara
Morocco
10000

Sponsor information

Organisation
SERVIER (Morocco)

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Sponsor type
Industry

Website
https://servier.ma/

Funder(s)

Funder type
Industry

Funder Name
SERVIER (Morocco)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
30/12/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed in the current study are not expected to be made available due to the data privacy of Morocco.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file		03/06/2023	28/03/2024	No	No