Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

HINTreat

Protocol summary

Study aim
The Hypertension Intensive Nutrition Treatment (HINTreat) trial was initiated with the aim of investigating the effects of a six-month intensive lifestyle treatment versus usual care, among patients with stage 1 essential hypertension.

Design
pragmatic, community based, parallel group, single blind randomized controlled trial

Settings and conduct
The intervention was home based

Participants/Inclusion and exclusion criteria
Inclusion criteria involved: 1) untreated stage 1 EH, 2) age> 18 years old, and 3) agreement to participate. Exclusion criteria were: 1) diagnosis of secondary hypertension, 2) diabetes mellitus, 3) cardiovascular disease (CVD), 4) any known inflammatory condition, 5) malignancy, 6) or other significant comorbidities affecting arterial BP, 7) treatment with antihypertensive agents or other significant medication, including diuretics.

Intervention groups
Patients were divided into two groups. Participants in the first group acted as controls, receiving baseline standard advise concerning lifestyle modifications,according to the ESH guidelines. The second group formed the intervention group, receiving intensive lifestyle treatment concerning nutrition modification and exercise, in accordance with the ESH guidelines. At baseline, the intervention group received a one-to-one a 1h nutrition education session with a dietitian , and a personalized diet plan. Emphasis was given on the dietary changes needed to be adhered, including an increase in fruit and vegetables consumption, a reduction in the salt intake, the effects of weight loss and the need for regular physical activity.

Main outcome variables
Office BP, 24h & Day BP (ABPM), carotid intima-media thickness (IMT), carotid stiffness, pulse wave velocity (PWV), lipid profile (Total Cholesterol, TG, HDL, LDL)

General information

Reason for update

Acronym
HINTreat

IRCT registration information
IRCT registration number: **IRCT20200307046715N1**
Registration date: **2020-03-14, 1398/12/24**
Registration timing: **prospective**

Last update: **2020-03-14, 1398/12/24**
Update count: **0**

Registration date
2020-03-14, 1398/12/24

Registrant information

Name
ANASTASIOS VAMVAKIS

Name of organization / entity
HYPERTENSION CLINIC, 3RD DEPARTMENT OF INTERNAL MEDICINE, MEDICAL SCHOOL, ARISTOTLE UNIVERSITY, THES

Country
Greece

Phone
+30 231 022 7623

Email address
tvamvakis@yahoo.gr

Recruitment status
Not yet recruiting

Funding source

Expected recruitment start date
2637-04-21, 2016/02/01

Expected recruitment end date
2640-05-17, 2019/02/27

Actual recruitment start date
2637-04-21, 2016/02/01

Actual recruitment end date
2640-09-21, 2019/06/30

Trial completion date

2640-09-21, 2019/06/30

Scientific title
HINTreat

Public title
Impact of diet plus exercise on endothelial function, arterial stiffness and blood pressure in stage 1 hypertensive patients: results from the HINTreat randomized, open-label trial

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Untreated stage 1 hypertensive Adults Agreed to participate

Exclusion criteria:
Diagnosis of secondary hypertension Diabetes Mellitus Cardiovascular Diseases Any known inflammatory condition Malignancy Other significant comorbidities affecting blood pressure Treatment with anti hypertensive agents or other significant medication including diuretics

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **91**
Actual sample size reached: **81**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization of participants to either the intensive lifestyle intervention treatment or the usual care group, was performed on blocks of 1, using the StatTrek software. Investigators, participants and statisticians were all aware of the allocation at every step of the progress.

Blinding (investigator's opinion)
Single blinded

Blinding description
Participants were not aware of the group allocation or of the existence of other groups with different treatment protocols. Each participant performed the baseline and follow-up measurements alone, therefore no contact was performed with other participants. None of the examiners provided information on the two different treatments to the participants.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Aristotle University |Ethical Committee

Street address
University Campus

City
Thessaloniki

Postal code
54624

Approval date
2637-06-13, 2016/03/23

Ethics committee reference number
2.169

Health conditions studied

1

Description of health condition studied
Hypertension

ICD-10 code
I10

ICD-10 code description
Essential (primary) hypertension

Primary outcomes

1

Description
blood pressure

Timepoint
baseline, 3 months, 6 months

Method of measurement
sphygmomanometer

2

Description
carotid intima-media thickness

Timepoint
baseline, 6 months

Method of measurement
ultrasound

3

Description
carotid stiffness

Timepoint
baseline, 6 months

Method of measurement
ultrasound

4

Description
pulse wave velocity
Timepoint
baseline, 6 months
Method of measurement
ABPM, Mobil-O-Graph

5

Description
lipid profile (Total Cholesterol, TG, HDL, LDL)
Timepoint
baseline, 6 months
Method of measurement
Fasting blood sample

Secondary outcomes

1

Description
Anthropometry changes (body weight, waist & hip circumference, body synthesis)
Timepoint
baseline, 6 months. For body weight and circumferences also at 3 months
Method of measurement
weight scale, measuring tape, bioelectrical impedance

2

Description
Physical activity level
Timepoint
baseline, 6 months
Method of measurement
IPAQ, pedometer

3

Description
Diet changes
Timepoint
baseline, 6 months. 24 hour recall used at 3 months
Method of measurement
(3day recall, 24hour recall, MedDiet score, DII score, salt score)

4

Description
Urinary losses in sodium, potassium, creatinine, microalbumin
Timepoint
baseline, 3 & 6 months
Method of measurement
24h urinary sample analysis

5

Description
Resting energy expenditure
Timepoint
baseline, 6 months
Method of measurement
Indirect calorimetry (Breezing)

Intervention groups

1

Description
Intervention group: receiving intensive lifestyle treatment concerning nutrition modification and exercise, in accordance with the ESH guidelines. In further detail, at baseline, the intervention group received a one-to-one a one hour nutrition education session with a registered dietitian, and a personalized diet plan. Emphasis was given on the dietary changes needed to be adhered, including an increase in fruit and vegetables consumption, a reduction in the salt intake, the effects of weight loss and the need for regular physical activity.
Category
Lifestyle

2

Description
Control group: receiving baseline standard advise concerning lifestyle modifications, according to the ESH guidelines, without having a personalized diet plan or nutrition education sessions.
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Papageorgiou General Hospital
Full name of responsible person
Anastasios Vamvakis
Street address
Ring road, New Efkarpia, Thessaloniki
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity

Mitropoleos 92 St

Full name of responsible person
Vamvakis

Street address
Ring road

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54622

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tvamvakis@yahoogr

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Mitropoleos 92 St

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
aristotle university of thessaloniki

Full name of responsible person
Anastasios Vamvakis

Position
researcher

Latest degree
Master

Other areas of specialty/work
Nutrition

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
participants might be identified
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
in one year
When the data will become available and for how long
in one year
To whom data/document is available
every reasonable request
Under which criteria data/document could be used
individual patient information protected
From where data/document is obtainable
nutrients journal
What processes are involved for a request to access data/document
ethical permission
Comments