

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 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 advice 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

City

Thessaloniki

Postal code

56429

Phone

+30 231 022 7623

Email

tvamvakis@yahoo.gr

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mitropoleos 92 St
Full name of responsible person
Vamvakis
Street address
Ring road
City
Thessaloniki
Postal code
54622
Phone
+30 231 022 7623
Email
tvamvakis@yahoo.gr
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
Street address
mitropoleos
City
thessaloniki
Province
thessaloniki
Postal code
54624
Phone
+30 231 022 7623
Email
tvamvakis@yahoo.gr
Web page address
<https://www.auth.gr>

Person responsible for scientific inquiries

Contact
Name of organization / entity
Aristotle University
Full name of responsible person
Anastasios Vamvakis
Position
Researcher
Latest degree
Master
Other areas of specialty/work
Nutrition
Street address
Mitropoleos
City
Thessaloniki
Province
Thessaloniki
Postal code
54624
Phone
+30 231 022 7623
Email
tvamvakis@yahoo.gr
Web page address
<https://www.auth.gr>

Person responsible for updating data

Contact
Name of organization / entity
Hypertension Clinic, 3rd Department of Internal Medicine, Medical School, Aristotle University
Full name of responsible person
Anastasios Vamvakis
Position
Researcher
Latest degree
Master
Other areas of specialty/work
Nutrition
Street address
Papageorgiou General Hospital, Ring Road, N. Eykarpia, 54603, Thessaloniki, Greece
City
Thessaloniki
Province
Thessaloniki
Postal code
54624
Phone
+30 231 022 7623
Fax
Email
tvamvakis@yahoo.gr

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