

# Effect of grape seed extract high in polyphenols on blood pressure in subjects with elevated blood pressure levels.

Published: 06-02-2009

Last updated: 06-05-2024

Primary objective: to study, in subjects with elevated blood pressure levels, the effects of an encapsulated grape seed extract high in polyphenols on daytime ambulatory systolic and diastolic blood pressure. Secondary objective: to explore...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Other condition
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON33721

### Source

ToetsingOnline

### Brief title

Grapeseed study

### Condition

- Other condition

### Synonym

high blood pressure, hypertension

### Health condition

risicofactor HVZ: verhoogde bloeddruk

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Unilever

**Source(s) of monetary or material Support:** Unilever financiert eigen onderzoek

## Intervention

**Keyword:** ambulatory blood pressure, blood pressure lowering, grapeseed, mechanistic markers

## Outcome measures

### Primary outcome

Mean ambulatory blood pressure, measured during 12 hours on 2 measurement days.

### Secondary outcome

Mechanistic markers

Urine metabolites

## Study description

### Background summary

Previous research showed that a grapeseed extract can reduce blood pressure. The present study will be performed to test, in a second independent study, whether or not a grapeseed extract has a blood pressure lowering effect. Next to that, some mechanistic markers will be measured when a blood pressure lowering effect is seen, which can provide insight into the mechanism of action.

### Study objective

Primary objective: to study, in subjects with elevated blood pressure levels, the effects of an encapsulated grape seed extract high in polyphenols on daytime ambulatory systolic and diastolic blood pressure.  
Secondary objective: to explore mechanistic pathways responsible for the blood pressure lowering efficacy.

### Study design

- placebo controlled, double blind, randomized parallel design
- 70 subjects
- 2 test products

capsules with grapeseed extract

placebo capsules

- 1 week run-in, 8 weeks intervention

The following measurements will take place at the end of run-in and at the end of intervention:

Day 1: 12h ambulatory blood pressure measurements (every 20 min)

Day 2: 24h urine collection, 2 blood samples (before and after breakfast)

Day 3: 12h ambulatory blood pressure measurements (every 20 min)

- dietary restrictions during complete study: max 2 cups of tea per day, no red wine, red grapejuice, dark chocolate, on certain days no alcoholic consumptions, repetition of meals on measurement days before and after intervention

## **Intervention**

Capsules with grapeseed extract

Placebo capsules

## **Study burden and risks**

There are, as far as known, no medical risks associated with participation to this study.

## **Contacts**

### **Public**

Unilever

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Nederland

### **Scientific**

Unilever

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Age 35-75 years

SBP 120-159 mmHg

BMI 18.5-30.0 kg/m<sup>2</sup>

### Exclusion criteria

Unilever employees

DBP > 99 mmHg

Smokers

Medical conditions or medicine use which may influence study parameters

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Other

## Recruitment

NL  
Recruitment status: Recruitment stopped  
Start date (anticipated): 23-04-2009  
Enrollment: 70  
Type: Actual

## Ethics review

Approved WMO  
Date: 06-02-2009  
Application type: First submission  
Review commission: METC Wageningen Universiteit (Wageningen)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

Register	ID
Other	nader te bepalen
CCMO	NL26071.081.08