# The effects of CasiGold and CasiMax on blood pressure in subjects with high-normal blood pressure or mild hypertension

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Other condition |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON30927

**Source**
ToetsingOnline

**Brief title**
Casigold and blood pressure

### Condition

- Other condition

**Synonym**
high blood pressure, hypertension

**Health condition**

verhoogde bloeddruk

**Research involving**

Human

## Sponsors and support

**Primary sponsor:** DSM Food Specialties
**Source(s) of monetary or material Support:** bedrijf (opdrachtgever)

## Intervention

**Keyword:** blood pressure, casein hydrolysate, IPP, tripeptides

## Outcome measures

### Primary outcome

The main study parameter is the blood pressure after 4 weeks of treatment.

Blood pressure will be measured at the study site on the two final treatment

days in last week of each treatment using automated digital sphygmomanometry

(OMRON IC) between 2.5 and 3.5 h after ingestion of the morning capsule.

### Secondary outcome

Secondary study parameters include evaluation of safety at the end of each

treatment, mechanistic parameters (renin, angiotensin I and II), and blood

pressure-related genetic polymorphisms.

# Study description

### Background summary

Hypertension is the major controllable risk factor associated with cardiovascular disease. The risk of developing CVD is directly related to blood pressure (BP) level. Tripeptides IPP and VPP obtained from milk proteins were shown to have potential blood lowering effects. The renin-angiotensin system is one of the major pathways of BP regulation, and ACE inhibiton is an important target for BP control. CasiGold and CasiMax are hydrolysed casein preparations consisting of relatively high concentrations tripeptides, in particular IPP, which have ACE inhibitory properties in vitro and which may have beneficial effects on blood pressure.

## Study objective

The primary objective is to demonstrate a blood pressure lowering effect of CasiGold and CasiMax in subjects with high-normal blood pressure or mild hypertension.

The secondary objectives are to collect human safety data after treatment with CasiGold and CasiMax, to gain insight into potential mechanisms by measurement of renin and angiotensin I and II, and to evaluate the blood pressure-related genetic determinants of the individual BP lowering response by measurement of specific genetic polymorphisms. Mechanistic parameters will only be measured in case a change in BP is found.

## Study design

The study is designed as a randomized, placebo-controlled, double-blind, cross-over study.

## Intervention

All subjects receive all treatments (cross-over), but in a different order (randomised). One of the treatments consists of daily consumption of two capsules Casigold containing in total 15 mg IPP during a period of 4 weeks. One of the treatments consists of daily consumption of two capsules Casimax containing in total 3.7 mg IPP, 4.6 mg LPP, and 13.2 mg MAP during a period of 4 weeks. And one of the treatments consists of daily consumption of two capsules placebo during a period of 4 weeks. One capsule will be taken upon completion of breakfast and one capsule will be taken upon completion of dinner.

## Study burden and risks

The study will be performed in subjects with high-normal blood pressure or mild hypertension, because these subjects are the target group for substances with a blood pressure lowering potential. Subjects need to visit the study site 6 times for blood pressure measurements, 3 times for collection of fasting blood and urine samples, and 4 times for collection of study substances. The total amount of blood collected during the study will be ca. 70 mL. At each visit, subjects need to fill in a short well-being questionnaire. During a period of 12 weeks subjects need to consume a capsule twice daily, to keep a diary, and to limit consumption of fermented dairy products.
The study substances are considered safe and no side effects are expected for the subjects. To be on the safe side, since one of the side effects of synthetic ACE-inhibitory drugs may be cough and, to lesser extent, skin rash, this will specifically be inquired on the well-being questionnaire.

# Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

1.Healthy as assessed by the TNO health and lifestyle questionnaire, physical examination, results of the pre-study laboratory tests;
2.Female and male Caucasians
3.Age 30 - 70 years at Day 01 of the study
4.Body Mass Index (BMI) 18 - 32 kg/m2
5.Blood pressure (automated BP measurements at site): SBP 120-139 mmHg/DBP 80-89 mmHg (pre-hypertension) or SBP 140-159/DBP 90-99 mmHg (stage 1 hypertension). Ratio pre-hypertension: stage 1 hypertension must be 1:1.
6.Normal Dutch eating habits; consuming mostly three main meals including breakfast and dinner
7.Voluntary participation
8.Having given their written informed consent

9.Willing to comply with the study procedures
10.Appropriate veins for blood sampling according to TNO
11.Willing to accept use of all nameless data, including publication, and the confidential use and storage of all data for at least 15 years
12.Willing to accept the disclosure of the financial benefit of participation in the study to the authorities concerned

### Exclusion criteria

1.Having a history of medical or surgical events that may significantly affect the study outcome, including cardiovascular disease or hypertension >=160/100 mm Hg after repeated measurements
2.Any concomitant medication, with the exception of paracetamol, that may influence the outcome of the study (e.g. ACE inhibitory drugs or other BP lowering medication)
3.Intolerance or allergy to milk products
4.Not willing to give up consumption of >1 fermented dairy product per day
5.Alcohol consumption > 28 units/week for males or > 21 units/week for females women)
6.Smoking
7.Reported unexplained weight loss or weight gain of > 2 kg in the month prior to pre-study screening
8.Reported slimming or medically prescribed diet
9.Reported vegan, vegetarian or macrobiotic life-style
10.Participation in night shift work
11.Pregnant or lactating or wishing to became pregnant in the period of the study
12.Recent blood or plasma donation (<1 month prior to Day 01 of the study)
13.Not willing to give up blood donation during the study
14.Personnel of TNO Quality of Life, their partner and their first and second degree relatives
15.Not having a general practitioner
16.Not willing to accept information-transfer concerning participation in the study, or information regarding a subject*s health (laboratory results, findings at anamnesis or physical examination and eventual adverse events) to and from a subject*s general practitioner.

## Study design

### Design

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| Study type: | Interventional |
| Intervention model: | Crossover |
| Allocation: | Randomized controlled trial |
| Masking: | Double blinded (masking used) |

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| Control: | Placebo |
| Primary purpose: | Treatment |

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 04-07-2007 |
| Enrollment: | 84 |
| Type: | Actual |

## Ethics review

Approved WMO

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| Application type: | First submission |
| Review commission: | METC Brabant (Tilburg) |

## 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 |
|---|---|
| CCMO | NL16945.028.07 |