# Het effect van drop op de bloeddruk, cortisol/cortison ratio en elektrolieten

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruiting |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON26713

**Source**
Nationaal Trial Register

**Brief title**
Licorice Influences on blood pressure, Cortisol/Cortisone, Electrolytes (LICORICE)

**Health condition**

Hypertension, Licorice, Pseudohyperaldosteronism, Hypokalemia

### Sponsors and support

**Primary sponsor:** None
**Source(s) of monetary or material Support:** fund = initiator = sponsor

### Intervention

### Outcome measures

**Primary outcome**

Systolic daytime ambulatory blood pressure

**Secondary outcome**

- Diastolic daytime ambulatory blood pressure, systolic and diastolic night-time blood

pressure and systolic and diastolic 24-hour ambulatory blood pressure

- Cortisol/cortisone ratio, potassium, sodium and aldosterone excretion in 24h urine collection

- Concentrations of plasma potassium, sodium, eGFR, creatinine, aldosterone and plasma renin activity

- Individual susceptibility, participants with significant changes will be considered by investigating the existence of genetic single nucleotide polymorphisms

- Heart rate (daytime, night-time and 24 hour)

- Changes in body weight

# Study description

### Background summary

Licorice contains glycyrrhizic acid, which is known to induce pseudohyperaldosteronism. Glycyrrhizic acid inhibits 11 beta hydroxylase activity and thereby reduces the selective conversion of cortisol to cortisone. Cortisol has a much higher affinity for the mineralocorticoid receptor compared to cortisone and causes activation of the mineralocorticoid receptors, resulting in hypertension, increased sodium retention, excessive renal potassium loss, low renin and reduced aldosterone levels. There is no worldwide consensus of the legal upper use limit specified for the maximum amount of glycyrrhizic acid that may be present in foods and supplements. The European Food Safety Authority (EFSA) determine a maximum level of glycyrrhizic acid in confectionery of 1500 mg/kg. However, this amount is often exceeded by manufacturers. A maximal level of 100 mg/person/day glycyrrhizic acid ingestion in adults is considered to be safe for the majority of the population, but many individuals exceed the recommended amount. Licorice induced hypertension has been focus of a few studies, but the individual susceptibility to licorice exposure and variations in blood pressure and urinary excretion of cortisol/cortisone ratio has not been systematically assessed

### Study objective

Licorice consumption leads to an increase in blood pressure that is associated with alterations in the cortisol/cortisone balance.

### Study design

Day 0: Visit 1: Screening

Day 14: Visit 2: Blood sampling, attaching ABPM, start urine collection, weight measurement

Day 15: Visit 3: Handing in ABPM and 24 hour urine collection

Day 22: Visit 4: Blood sampling, attaching ABPM, start urine collection, weight measurement

Day 23: Visit 5: Handing in ABPM and 24 hour urine collection

**Intervention**

Licorice with an amount of 300 mg glycyrrhizic acid a day for seven (7) days

# Contacts

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# Eligibility criteria

## Inclusion criteria

- Willing and able to participate in the study protocol

- Written informed consent

- Age 18-60 years

- BMI > 18 or < 35 g/m2

- Willing to adhere to the study protocol

- Accessible veins on arm(s) as determined by examination at information meetings

### Exclusion criteria

- Allergy to one of the ingredients of licorice

- Office blood pressure >140/90 mmHg

- Reported alcohol consumption > 28 units/week or recreational drug use

- Existing cardiovascular diseases

- Use of medication which affects the primary or secondary outcome measurements such as diuretics, antihypertensive drugs and NSAIDs for at least six weeks before start of the study

- Currently on a medically prescribed diet, or slimming diet

- Potassium <3.5 mmol/l

- eGFR <60 mL/min/1.73 m2

- Excessive ingestion of licorice (>200 gr/week) or >3 litre of licorice tea per week

- Pregnancy

## Study design

### Design

| | |
|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Non controlled trial |
| Masking: | Open (masking not used) |
| Control: | N/A , unknown |

### Recruitment

NL
Recruitment status: Recruiting

| | |
|---|---|
| Start date (anticipated): | 01-02-2018 |
| Enrollment: | 40 |
| Type: | Anticipated |

## Ethics review

| | |
|---|---|
| Positive opinion<br>Date: | 30-04-2018 |
| Application type: | First submission |

## Study registrations

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

ID: 46407
Bron: ToetsingOnline
Titel:

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

No registrations found.

### In other registers

| Register | ID |
|---|---|
| NTR-new | NL6991 |
| NTR-old | NTR7181 |
| CCMO | NL64405.018.17 |
| OMON | NL-OMON46407 |

## Study results