

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

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26713

Bron

NTR

Verkorte titel

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

Aandoening

Hypertension, Licorice, Pseudohyperaldosteronism, Hypokalemia

Ondersteuning

Primaire sponsor: None

Overige ondersteuning: fund = initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Systolic daytime ambulatory blood pressure

Toelichting onderzoek

Achtergrond van het onderzoek

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

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

Bert-Jan H. van den Born
Departments of Internal & Vascular Medicine; Academic Medical Center (AMC); University of Amsterdam; Meibergdreef 9, Room F4-109;
Amsterdam 1105 AZ
The Netherlands
+31 20 566 5956 / +31 20 566 9111/58070

Wetenschappelijk

Bert-Jan H. van den Born
Departments of Internal & Vascular Medicine; Academic Medical Center (AMC); University of Amsterdam; Meibergdreef 9, Room F4-109;
Amsterdam 1105 AZ
The Netherlands
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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-02-2018
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum: 30-04-2018

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 46407

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten