Het acute effect van beta-guanidinopropionzuur en creatine

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

Samenvatting

ID

NL-OMON26749

Bron
Nationaal Trial Register

Verkorte titel
ABC trial

Aandoening

In this randomized, placebo controlled, double blind trial, we will assess the acute effect of the food supplements beta-guanidinopropionic acid and creatine in healthy men.
Keywords: Healthy volunteers, creatine, beta-guanidinopropionic acid, tolerability, blood pressure, haemodynamics, ADP-dependent platelet aggregation.
In Dutch: gezonde vrijwilligers, creatine, beta-guanidinopropionzuur, tolerantie, bloeddruk, haemodynamiek, ADP-afhankelijke plaatjesaggregatie.

Ondersteuning

Primaire sponsor: The principal investigator is the study sponsor
Overige ondersteuning: fund = initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Tolerability of GPA after oral administration in healthy male volunteers versus placebo

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Beta-guanidinopropionic acid (GPA), a creatine analogue, can be obtained without prescription on the internet, and is used by sportsmen to increase muscle mass and endurance capacity. In contrast, creatine is used to improve short-duration/high-intensity exercise.
Although previous studies assessed the effect on muscle performance of creatine in humans, and of GPA in animals, none of these studies reported the effect on peripheral hemodynamic parameters, or the effect on ADP-dependent platelet aggregation. Our new data from animal studies indicate an anti-hypertensive effect of GPA. However, to our knowledge, there are no published human data on the effects and side effects of GPA.

Objective: In this study we will assess in human volunteers, the tolerability of GPA 100 mg during 1 week, as a primary outcome, compared to placebo and creatine 5 g.

Study design: Randomized, double-blind, placebo-controlled,

double-dummy intervention study.

Study population: 24 healthy male volunteers, 18-50 years old recruited in the Netherlands.

Intervention: One week of daily oral administration of GPA 100 mg, creatine 5 g, or placebo.

Main study parameters/endpoints: Tolerability for GPA assessed with a questionnaire; hemodynamic parameters, including blood pressure, heart rate, cardiac output and total peripheral resistance; biochemical parameters, including serum CK, GPA, creatine, glucose, insuline, creatinine after acute oral administration of GPA and one week of intervention with GPA or creatine; ADP-induced platelet aggregation.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: In this study, we will assess the effects of GPA, a freely available creatine analogue, and creatine in healthy subjects. This will not directly benefit the participants. The risks associated with participation can be considered negligible and the burden can be considered minimal.

Doel van het onderzoek

Beta-guanidinopropionic acid (GPA), a creatine analogue, can be obtained without prescription on the internet, and is used by sportsmen to increase muscle mass and endurance capacity. In contrast, creatine is used to improve short-duration/high-intensity exercise. Although previous studies assessed the effect on muscle performance of creatine in humans, and of GPA in animals, none of these studies reported the effect on peripheral hemodynamic parameters. Our new data indicate a potential blood pressure lowering effect

of GPA in hypertensive animals. However, to our knowledge, there are no published human data on the effects and side effects of GPA.

Therefore, in this RCT we will assess in human volunteers, the tolerability of GPA as a primary outcome, and the haemodynamic effects in comparison with creatine as a secondary outcome.

Onderzoeksopzet

T=0 Baseline measurements (before intake of trial supplements or placebo)

Primary outcome: General history taking

Secondary Outcome:

Hemodynamic parameters (Resting blood pressure; heart rate, cardiac output and total peripheral resistance, measured non-invasively) and ADP-induced platelet aggregation.

T=2 days (After 1 day of use of trial supplements or placebo)

Primary Outcome: The probability of adverse drug reactions will be estimated with the validated Naranjo adverse drug reaction probability scale.

Secondary Outcome:
Hemodynamic parameters (Resting blood pressure; heart rate, cardiac output and total peripheral resistance, measured non-invasively)

T=7 days (after 7 days of use of trial supplements or placebo)

Primary Outcome: The probability of the adverse drug reactions will be estimated with the validated Naranjo adverse drug reaction probability scale.

Secondary Outcome:
Hemodynamic parameters (Resting blood pressure; heart rate, cardiac output and total peripheral resistance, measured non-invasively) and ADP-induced platelet aggregation.

T=21 days, 2 weeks after stopping the use of trial supplements or placebo

Primary Outcome: The probability of adverse drug reactions will be estimated with the

validated Naranjo adverse drug reaction probability scale.

Onderzoeksproduct en/of interventie

The participants will be asked to come to the hospital an overnight fasts.

At visit 1 (day 0), after baseline measurements, they will receive a 24 h blood pressure measurement device and a container to collect 24h urine.

At visit 2, the next day (day 1 of the trial supplements), they will take first capsules with GPA 100 mg, creatine 5 g, or placebo in the hospital (Figure 4B) after receiving a 24 h blood pressure measurement device and a container to collect 24h urine.

At visit 3 (day 2 of the trial supplements), haemodynamic and blood tests will be performed, trial supplements will be taken, and participants will receive trial supplements to take at home at day 3, 4,5, and 6 after an overnight fast.

The participants return to the hospital for visit 4 at day 7 of the trial supplements, to take the final trial supplements after receiving a 24 h blood pressure measurement device and a container to collect 24h urine.

They will return for visit 5 on day 8 for haemodynamic measurements and blood tests.

The 6th and last visit is at day 21, for the final assessment of tolerability.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Healthy men, 18-50 years old, with a body mass index from 18.5 to 29.9 kg/m2

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

glucose, lipid spectrum, thyroid, kidney, or liver abnormalities, (history of) cardiovascular disease including TIA and stroke; CK-increasing drugs including statins; use of acetylsalicyl acid or non-steroidal anti-inflammatory drugs (NSAIDs) in the two week prior to the visits, neuromuscular or endocrine disorders; vasculitis; HIV infection; infectious hepatitis; personal or family history of bleeding disorders, sickle cell disease; smoking; current use or use within 2 months prior to start of the trial of beta-guanidinopropionic acid or creatine.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland
Status: Werving gestopt

(Verwachte) startdatum:	13-03-2014
Aantal proefpersonen:	24
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	09-03-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 39788
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4299
NTR-old	NTR4444
CCMO	NL38368.018.12
OMON	NL-OMON39788

Resultaten