HORSE trial

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

Samenvatting

ID

NL-OMON22116

Bron
Nationaal Trial Register

Verkorte titel
HORSE

Aandoening

veisalgia (hangover)

Ondersteuning

Primaire sponsor: Afdeling Experimentele Oncologie AMC
1105 AZ Amsterdam
Overige ondersteuning: Afdeling Experimentele Oncologie AMC
1105 AZ Amsterdam

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Main study parameter is the subjective feeling of well being as evaluated by the questionnaire.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Development of veisalgia, or hangover, is a frequent event after a night of drinking. Hangovers are typically characterized by headache, nausea and diminished feeling of general well-being. Next to personal disadvantages, it has been suggested that the economical consequences of hangovers are severe. Several studies investigated possible pathogenic mechanisms for hangovers. Of these mechanisms, dehydration is an accepted cause for a hangover. Alcohol inhibits release of anti-diuretic hormone what leads to dehydration. The correlation between alcohol intake and dehydration is observed in several studies. ORS, Oral Rehydration Solution is a reliable treatment for dehydration. The link between ORS and relieve of veisalgia has been suggested by several sources, although evidence was never generated.

Objective: This trial should provide evidence for reduced symptoms of veisalgia after preventive intake of ORS (Oral Rehydration Solution) after drinking alcoholic beverages.

Study design: Randomized placebo controlled double-blind intervention study.

Study population: 200 healthy volunteers age 18 – 65.

Intervention: Volunteers are asked to participate prior to engaging in a social event. When leaving the event, participants will consume ORS or placebo. The next day, all subjects are asked to fill in a questionnaire concerning veisalgia, an adapted version of the Acute Hang Over Scale.

Main study parameters/endpoints: Main study parameter is the subjective feeling of well being as evaluated by the questionnaire. Secondary parameter is the influence of alcohol intake on severity of veisalgia.

Doel van het onderzoek

The correlation between alcohol intake and dehydration is observed in several studies. ORS, Oral Rehydration Solution is a reliable treatment for dehydration. The link between ORS and relieve of veisalgia has been suggested by several sources, although evidence was never generated.

Onderzoeksopzet

1 time point the morning after the intervention

Onderzoeksproduct en/of interventie

Volunteers are asked to participate prior to engaging in a social event. When leaving the

event, participants will consume ORS or placebo. The next day, all subjects are asked to fill in a questionnaire concerning veisalgia, an adapted version of the Acute Hang Over Scale.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age 18 – 65

2. Signed informed consent when sober (breathalyzer promillage is < 0.5)

3. Participant has had hang over before and recognizes the symptoms headache, nausea and a diminished feeling of general well-being

4. Participant has access to the internet shortly after waking up

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

1. Pregnancy

2. Alcohol promillage by breathalyzer when intake of placebo or ORS > 2.0

3. Participant has inability to comply with protocol or study procedures (for example, an inability to swallow fluids)

4. Participant is at this moment under treatment by medical specialist

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	18-03-2008
Aantal proefpersonen:	200
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	06-06-2008
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1292
NTR-old	NTR1339
Ander register	: MEC 090/071 # 08.17.0405
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A