Binding interaction of polystyrene sulfonate and amitriptyline

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Polystyrene sulfonate shows an in-vitro binding interaction with amitriptyline, causing 70-80% binding of amitriptyline to polystyrene sulfonate. The hypothesis is that polystyrene sulfonate binds to amitriptyline when taken simoultaneously in...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26934

Bron
NTR

Verkorte titel
The BIND-study

Aandoening

drug-drug interaction
chronic renal failure
depression
neuropathic pain

Ondersteuning

Primaire sponsor: Deventer Ziekenhuis
Overige ondersteuning: Deventer Ziekenhuis, investigator initiated

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To determine whether polystyrene sulfonate has an effect on exposure of amitriptyline, when taken simultaneously, compared to amitriptyline taken alone in healthy volunteers, expressed in Cmax and AUC0-8h.

Toelichting onderzoek

Achtergrond van het onderzoek

The resin polystyrene sulfonate is often used for binding potassium for prevention of hyperkalaemia. Because of their binding properties, resins could potentially bind other medications before they can be absorbed completely and thereby decrease their bioavailability. This is confirmed in in vitro binding interaction studies. Our own in vitro research has shown a binding interaction between polystyrene sulfonate and amitriptyline. More information is needed on this possible binding interaction to use amitriptyline and polystyrene sulfonate effectively and safely.
The objective is to determine the effect of the binding interaction, that was found in vitro, on drug exposure in healthy volunteers when amitriptyline and polystyrene sulfonate are used simultaneously.
The study design is a prospective, cross-over trial in healthy volunteers.
Main study parameter: Difference in exposure of amitriptyline in the presence and absence of polystyrene sulfonate, expressed in Cmax and AUC0-8h.
The participants will visit the hospital twice. Both times they will receive a single dose of amitriptyline and once they will receive polystyrene sulfonate concomitantly. Six blood samples will be collected, taken from a peripheral intravenous catheter, at each visit.

Doel van het onderzoek

Polystyrene sulfonate shows an in-vitro binding interaction with amitriptyline, causing 70-80% binding of amitriptyline to polystyrene sulfonate. The hypothesis is that polystyrene sulfonate binds to amitriptyline when taken simoultaneously in healthy volunteers, leading to decreased exposure to amitriptyline.

Onderzoeksopzet

After intake of amitriptyline with/without polystyrene sulfonate

Onderzoeksproduct en/of interventie

Intake of amitriptyline alone and amitriptyline with polysytrene sulfonate

Contactpersonen

Publiek

Deventer ziekenhuis
Ilona Prins-Can

0570536242

Wetenschappelijk

Deventer ziekenhuis
Ilona Prins-Can

0570536242

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- The participant is at least 18 years of age

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Known allergy to one of the investigated substances
- Known renal or hepatic impairment
- Pregnancy
- Breast feeding
- Use of other medication within 24 hours of the study period (oral contraceptives within 12 hours of the study period)
- Contra-indication for one of the investigated substances (such as recent myocardial infarction, cardiac arrhythmias, hypokalaemia and obstructive bowl disease)
- History of a gastro-intestinal condition that may interfere with absorption of amitriptyline

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-08-2020
Aantal proefpersonen:	9
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL8539
Ander register	METC Isala : 200411

Resultaten