Binding interaction of polystyrene sulfonate and amitriptyline

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26934

Source
NTR

Brief title
The BIND-study

Health condition

drug-drug interaction
chronic renal failure
depression
neuropathic pain

Sponsors and support

Primary sponsor: Deventer Ziekenhuis
Source(s) of monetary or material Support: Deventer Ziekenhuis, investigator initiated

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

not applicable

Study description

Background summary

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.

Study objective

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.

Study design

After intake of amitriptyline with/without polystyrene sulfonate

Intervention

Intake of amitriptyline alone and amitriptyline with polysytrene sulfonate

Contacts

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Eligibility criteria

Inclusion criteria

- The participant is at least 18 years of age

Exclusion criteria

- 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

Study design

Design

Study type:	Interventional
Intervention model:	Crossover

Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2020
Enrollment:	9
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8539
Other	METC Isala : 200411

Study results