Assessing the binding interaction of polystyrene sulfonate with amitriptyline in healthy volunteers;The BIND-study

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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.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON49827

Source
ToetsingOnline

Brief title
BIND

Condition

- Other condition

Synonym
drug-drug interaction study

Health condition

betreft interactiestudie in gezonde vrijwilligers.

Research involving
Human

Sponsors and support

Primary sponsor: Deventer Ziekenhuis
Source(s) of monetary or material Support: Deventer ziekenhuis

Intervention

Keyword: amitriptyline, binding interaction, polystyrene sulfonate

Outcome measures

Primary outcome

Difference in exposure of amitriptyline in the presence and absence of

polystyrene sulfonate, 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 interactions to use amitriptyline and polystyrene sulfonate effectively and safely.

Study objective

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.

Study design

A prospective, cross-over trial in healthy volunteers

Intervention

Healthy volunteers will receive a single dose of amitriptyline 50mg twice. Once simultaneously with polystyrene sulfonate 15grams and once without polystyrene sulfonate. There will be a wash out period of at least one week.

Study burden and risks

The study involves healthy volunteers. 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 at each visits. Both amitriptyline and polystyrene sulfonate are all licensed products with a known mechanism of action and known side effects. Because it involves a single dose of the substances, the risk is low.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

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 phase:	4
Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-08-2020
Enrollment:	9
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Kayexalate
Generic name:	Sodium polystyrene sulfonate
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Sarotex
Generic name:	Amitriptyline
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	23-04-2020
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	14-05-2020
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

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
EudraCT	EUCTR2020-001569-36-NL
CCMO	NL73647.075.20