Co-trimoxazol induced hyperkalemia

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21992

Source
NTR

Brief title
N/A

Health condition

Hyperkalemia
Antibiotic treatment
Adverse drug reaction

Sponsors and support

Primary sponsor: Canisius Wilhelmina Hospital, department of Clinical Pharmacy, Nijmegen, the Netherlands
Source(s) of monetary or material Support: Canisius Wilhelmina Hospital, department of Clinical Pharmacy, Nijmegen, the Netherlands

Intervention

Outcome measures

Primary outcome

We will compare the surges in serum potassium levels of both groups. We will compare these surges in serum potassium by measuring serum potassium before and after the start of antibiotic treatment.

Secondary outcome

We will measure several secondary outcomes, including serum creatinin (before and after the start of antibiotic treatment), the incidence of hyperkalemia, co-factors that influence serum potassium, the amount of serum potassium measurements (before and after the initiation of antibiotic therapy, as a variable to measure medication safety), hyperkalemia-associated complications such as mortality and a possible dose-response effect on serum potassium in the co-trimoxazole group.

Study description

Background summary

This study aims to compare average serum potassium surges in hospitalized patients receiving intravenous co-trimoxazole with patients receiving intravenous ceftriaxone. New information regarding this ADR might lead clinicians to be able to make a better risk estimation regarding co-trimoxazole-induced hyperkalemia. We propose a retrospective cohort study in ± 100 adult subjects. We will compare an experimental group on co-trimoxazole (n = ± 50) with a control group on ceftriaxone (n = ± 50). We choose ceftriaxone as our control group because of its lack of effect on serum potassium, its widespread usage in infectious pathology and its partially overlapping indications with co-trimoxazole. Patients will be included if they received a sufficient dose of either intravenous ceftriaxone or intravenous co-trimoxazole for at least two days during their admission to the Canisius Wilhelmina Hospital in the time period of 2013 until 2015. Ceftriaxone patients will be included in a paired fashion with co-trimoxazole patients, based on admission department and time of antibiotic therapy. Patients will be excluded if their serum potassium levels are unreliable due to for example acid-base disorders. According to our pre-study power analysis, we need to include at least 88 patients with complete serum potassium measurements. We decided to aim for the inclusion of ± 100 patients with complete serum potassium values. Patients will be included only in the Netherlands. The primary outcome for both groups will be average serum potassium surge. Since hyperkalemia is a multifactorial disease, several possible confounders will be measured. These include, amongst others, serum potassium before antibiotic treatment, renal dysfunction and the usage of various medications such as angiotensin converting enzyme inhibitors, angiotensin receptor antagonists and diuretics. In short, we aim to give an estimation of serum potassium levels in hospitalized patients who receive intravenous co-trimoxazole, as compared to patients using intravenous ceftriaxone.

Study objective

Several studies have looked into hyperkalemia as adverse drug reaction of co-trimoxazole. Many of these previous studies have shown that co-trimoxazole induced hyperkalemia is a potentially dangerous adverse drug reaction, especially in high-risk groups. Since hyperkalemia can lead to palpitations, arrhythmias and, in severe cases, death, knowledge of this adverse drug reaction is vital for its safe application in medical practice. This study aims

to broaden the knowledge of co-trimoxazole induced hyperkalemia by observing and comparing serum potassium levels in hospitalized patients receiving either intravenous co-trimoxazole (experimental group) or ceftriaxone (control group).

Study design

Surge in serum potassium will be defined as the serum potassium after initiation of antibiotic therapy, minus the serum potassium before initiation of antibiotic therapy. The serum potassium before antibiotic treatment initation will be defined as the serum potassium on the initiation day, whereas the serum potassium after antibiotic treatment initiation will be defined as the highest serum potassium during treatment, within the time scope of 48-120h after initation. Secondary endpoints will also largely be measured either close to the day of initiation of antibiotic therapy, or during the period of antibiotic therapy. All data will be collected retrospectively using the electronic medical records.

Intervention

We will compare several parameters in two groups. Our experimental/intervention group will consist of patients admitted to the Canisius Wilhelmina hospital who receive at least 1920mg of intravenous co-trimoxazol per 24h for at least 48h. Our active control group will consist of patients admitted to the Canisius Wilhelmina hospital who receive at least 2g of intravenous ceftriaxone per 24h for at least 48h.

Contacts

Public

Scientific

Eligibility criteria

Inclusion criteria

- Admission date to the Canisius Wilhelmina hospital in the period of January 1st 2013 until December 31st 2015

- Receiving at least 1920mg intravenous co-trimoxazole per 24h for at least 48h or at least 2g intravenous ceftriaxone per 24h for at least 48h

Exclusion criteria

- Age under 18 years at the day of start of antibiotic treatment

- Admission to the intensive care unit during the antibiotic treatment period

- Severe kidney disease (defined as at least one measurement of < 30ml/kg/h during the antibiotic treatment period)

- (Moderately) severe acid-base disorders (defined as at least one measurement of pH < 7,25 or pH > 7,55 during the antibiotic treatment period)

- Simultaneous administration of both co-trimoxazole and ceftriaxone during the antibiotic treatment period.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	19-11-2018
Enrollment:	100
Type:	Anticipated

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	NL7343
NTR-old	NTR7608
Other	Canisius Wilhelmina hospital : 064-2018

Study results

Summary results
N/A