ISRCTN52852596 https://doi.org/10.1186/ISRCTN52852596

Adherence to, knowledge and beliefs about drugs used to reduce phosphate absorption in dialysis patients

Submission date
10/04/2019

Recruitment status
No longer recruiting

Registration date
11/04/2019

Overall study status
Completed

Last Edited
02/09/2020

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The majority of dialysis patients are using phosphate binders to prevent or reduce high phosphate blod levels. In this study we want to investigate adherence to, knowledge and beliefs about phosphate binder treatment in dialysis patients. We also want to investigate whether counselling about phosphate binder treatment changes these parameters and the phosphate blod levels.

Who can participate?
Dialysis patients aged 18 years or more, attending the Dialysis centre at Akershus unitversitetssykehus, can participate in the study.

What does the study involve?
All participants in the study will receive a one-to.one pharmacist-led education and counselling session. All participants will answer three questionnaires twice. These include questions about phosphate binders, adherence to phosphate binder treatment and beliefs about phosphate binder treatment.

What are the possible benefits and risks of participating?
The study is assumed to be of potential benefit for the participants by improving their knowledge about phosphate binders and their awareness of the importance of phosphate binder treatment.
There are no risks of participating in the study. Participation includes counselling by a pharmacist about phosphate binder treatment. Participants need to spend a bit of time answering questionnaires, during dialysis.

Where is the study run from?
The study is a cooperation between the Hospital pharmacy and the Dialysis centre at Akershus unversitetssykehus.

When is the study starting and how long is it expected to run for?
The study started in May 2017 and the approximate duration of the trial was two months.

Who is funding the study?
The Hospital Pharmacies Enterprise, South Eastern Norway are paying the costs that the trial will incur.

Who is the main contact?
If you have any questions regarding the study, please contact Bodil Jahren Hjemas, bodil.jahren.hjemas@sykehusapotekene.no

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2016/1996/REK sør-øst

Study information

Scientific Title
Interventional study to improve adherence to phosphate binder treatment in dialysis patients

Study objectives
A one-to-one pharmacist-led education and counselling can enhance adherence and lead to changes in serum phosphate in dialysis patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/12/2016, The Regional Committee for Medical and Health Research Ethics, REK sør-øst (Postboks 1130, Blindern, 0318 Oslo; +47 22 84 55 11; rek-sorost@medisin.uio.no), ref: 2016/1996

Study design
A descriptive interventional single-centre single arm pre-post study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Kidney disease requiring dialysis

Interventions

Patients included in the study received a single half-hour one-to-one pharmacist-led education and personalized counselling session. A semi-structured counselling guide was used in the session. An educational leaflet based on this guide was offered to the included patients.

Intervention Type
Behavioural

Primary outcome measure
Change in the proportion of patients with serum phosphate below 1.80 mmol/L. Serum phosphate levels for five months prior to the intervention, and five months after were drawn from the medical records for included patients.

Secondary outcome measures
Change in the patient's knowledge, beliefs and adherence after the intervention measured by completion of questionnaires:
'Patient Knowledge'
'Medication Adherence Report Scale'
'Beliefs about Medicines Questionnaire'
The participants were asked to answer the questionnaires twice; at the time of inclusion and 3 - 4 weeks after the intervention.

Overall study start date
20/01/2016

Completion date
31/12/2017

Eligibility

Key inclusion criteria
1. Age>18 years
2. Receiving chronic dialysis two to four times a week for at least five months
3. Using at least one self-administered phosphate binder
4. Able to speak, read and write Norwegian
5. Able to give informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

At study start 122 patients attended the hospital dialysis centre.

Total final enrolment
69

Key exclusion criteria
1. Life expectancy < 5 months

Date of first enrolment
22/05/2017

Date of final enrolment
27/06/2017

Locations

Countries of recruitment
Norway

Study participating centre
Akershus universitetssykehus HF Akershus University Hospital
Postboks 1000
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Norway
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Sponsor information

Organisation
The Hospital Pharmacies Enterprise, Sout Eastern Norway

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Sponsor type
Other

Website
https://sykehusapotekene.no/

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
The Hospital Pharmacies Enterprise

Results and Publications

Publication and dissemination plan
We wish to submit a manuscript for publication in BMC Nephrology in spring 2019, including the main results from the study.

Intention to publish date
15/04/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	17/05/2019	02/09/2020	Yes	No