

A randomised controlled two part study to evaluate the effectiveness of different education methods to achieve serum phosphate levels set by the Renal Association for haemodialysis patients.

Submission date 12/09/2003	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 12/09/2003	Overall study status Completed	☐ Statistical analysis plan
		☒ Results
Last Edited 29/04/2010	Condition category Urological and Genital Diseases	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Miss Dawn Yokum

Contact details
Department of Nutrition & Dietetics
59 Philpot Street
The Royal London Hospital
Whitechapel
London
United Kingdom
E1 1BB
+44 020 7377 7735
dawn.yokum@bartsandthelondon.nhs.uk

Additional identifiers

Protocol serial number
N0205118456

Study information

Scientific Title

Study objectives

To achieve good serum phosphate control in haemodialysis patients compliance with a phosphate restricted diet and phosphate binder medication is important. The aim of this project is to evaluate the effectiveness of different education methods including group teaching sessions and intensive phosphate clinics. We hope to find the best methods of educating people to achieve the desired levels.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Urological and Genital Diseases: Haemodialysis

Interventions

68 patients will be recruited and randomised into 4 groups. Baseline data on their phosphate knowledge and routine blood chemistry will be obtained. Two groups will attend group education sessions run by the renal dietician and the renal pharmacist. The other two groups will act as controls. At the end of this phase the phosphate questionnaire will be repeated and blood will be taken for analysis. The patients will then complete a 1 month wash-out phase. At the end of this they will repeat the questionnaire and have blood taken. Two groups will attend monthly intensive phosphate clinics for a 4 month period. The other two groups will act as controls. The questionnaire and blood test will be repeated at the end of this phase which is also the end of the study.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Group 1 (both interventions): results for phosphate knowledge and serum phosphate control should be the best out of all the groups

Groups 2 + 3 (each had one intervention only, group teaching session and intensive clinic respectively): results for phosphate knowledge and serum phosphate control should improve versus baseline

Group 4 (control): results for phosphate knowledge and serum phosphate control should be similar to baseline

Key secondary outcome(s)

Not provided at time of registration

Completion date

04/11/2004

Eligibility

Key inclusion criteria

Patients will be recruited from Barts and The London NHS Trust haemodialysis population. This includes hospital and satellite units. Inclusion criteria:

1. Serum phosphate: >1.7 mmol/l
2. Serum calcium: 2.2 - 2.6 mmol/l
3. Serum parathyroid hormone (PTH): 10-50 pmol.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

04/11/2002

Date of final enrolment

04/11/2004

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
Department of Nutrition & Dietetics
London
United Kingdom
E1 1BB

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
Barts and The London NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2008		Yes	No