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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Not Specified

Participant information sheet

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 measure
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

Secondary outcome measures
Not provided at time of registration

Overall study start date
04/11/2002

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
68

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
England

United Kingdom

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

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type

Government

Funder Name
Barts and The London NHS Trust (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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