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Exploring end stage renal disease patients' beliefs about phosphate binding medication and intervening to improve their adherence.

Submission date	Recruitment status	[_] Prospectively registered
30/09/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/09/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
22/07/2009	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

Protocol serial number
N0013146110

Study information

Scientific Title

Study objectives
Initially, a small pilot study of qualitative design will be carried out. The aim of this first part of the study will be to explore renal patients' concept of the mechanisms by which phosphate binding medication works and how this type of medication should be used. During the second stage, an intervention targeting patients' non-adherence with phosphate binding medication undergoing renal replacement therapy will be implemented. The intervention will be psycho educational and have as an aim to assist patients to change treatment related beliefs important in shaping medication adherence behaviour.

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)
Other

Health condition(s) or problem(s) studied
Urological and Genital Diseases: Renal disease

Interventions
An interview schedule will provide the framework for the semi-structured interviews conducted for the purpose of the first part of the study. The intervention will involve a demonstration of mixing a solution of phosphate binding medication in a phosphate solution with an accompanying explanation of how this treatment is beneficial to renal patients. A randomised controlled trial design will be followed with patients being allocated to receive either the intervention or treatment as usual. Phosphate levels will be obtained via the patients' notes, together with other outcome measures. These will be analysed and compared with the baseline measures previously recorded so that the effectiveness of the intervention in terms of improving adherence can be evaluated.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Laboratory blood measurements obtained from patient notes at baseline and at 3-month follow up will serve as outcome measures together with measures such as patients' satisfaction with information regarding this treatment and understanding of the nature of treatment.

Key secondary outcome(s)
Not provided at time of registration

Completion date
01/06/2004

Eligibility

Key inclusion criteria
Approx. 90 (10 for the qualitative study and 80 for the intervention) patients will be recruited from the Renal Unit at Guy's Hospital. Patients asked to participate will be kidney failure patients on renal replacement therapy (haemodialysis). For patients to be included in the study, they have to be undergoing dialysis for at least six months and be on phosphate binding medication.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/12/2003

Date of final enrolment
01/06/2004

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Guy's & St Thomas' NHS Foundation Trust
London
United Kingdom
SE1 9RT

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Guy's and St. Thomas' NHS Foundation Trust (UK)

Funder Name
Own account

Funder Name
NHS R&D Support Funding

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	01/05/2008		Yes	No