

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

Submission date 30/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 30/09/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 22/07/2009	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

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

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

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

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 measure

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.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/12/2003

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

Age group

Not Specified

Sex

Not Specified

Target number of participants

90

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

England

United Kingdom

Study participating centre

Guy's & St Thomas' NHS Foundation Trust

London

United Kingdom

SE1 9RT

Sponsor information

Organisation

Department of Health

Sponsor details

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

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dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

<http://www.dh.gov.uk/Home/fs/en>

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

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	01/05/2008		Yes	No