

Correction of acidosis in chronic kidney disease (CKD)

Submission date 03/12/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 18/01/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 04/07/2011	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

Protocol serial number
P/01/211

Study information

Scientific Title
Effects on progression of renal failure and nutritional status by correction of metabolic acidosis in patients with non-dialysis dependent chronic kidney disease (CKD)

Study objectives

Experimental data suggest that acidosis induced excessive renal ammoniagenesis and activation of the complement cascade by the alternative pathway, lead to rapid progression of renal failure which can be attenuated by bicarbonate supplementation. Moreover, metabolic acidosis accelerates protein catabolism and causes malnutrition due to an induced negative nitrogen balance in patients with end-stage renal disease (ESRD). We propose that correction of acidosis will attenuate the progression of renal failure and will improve nutritional status in patients with non-dialysis dependent chronic kidney disease.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The study is approved by the Local Research Ethics Committee from April 2002 to July 2006 (ref: P/01/211).

Study design

Randomised prospective parallel group study of patients in stage 4 and 5 CKD

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Chronic kidney disease

Interventions

Sodium bicarbonate versus no treatment.

Duration of treatment: 2 years

Method of intake: oral

Frequency of treatment: daily 600 mg three times a day to be titrated up by 600 mg till serum bicarbonate level of greater than 21 mmol/l were achieved

Duration of follow up: 2 years

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Sodium bicarbonate

Primary outcome(s)

The primary end points were number of patients reaching ESRD and rate of decline of estimated glomerular filtration rate (eGFR) by Cockcroft-Gault equation and creatinine clearance (Cr Cl) (24 hours urine sample).

Primary end points are measured every three months.

Key secondary outcome(s))

Nutritional parameters assessed by:

1. Dietary protein intake
2. Protein catabolic rate (PCR)
3. Serum albumin
4. Mid-arm muscle circumference (MAMC)

Secondary end points measured every six months.

Completion date

30/07/2006

Eligibility**Key inclusion criteria**

1. Age greater than 18 years old
2. CKD stage 4 and 5
3. Mild to moderate metabolic acidosis (serum bicarbonate less than 21 and greater than 16 mmol/L) on two consecutive measurements
4. Stable clinical condition

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

Patients with:

1. Malignant disease
2. Morbid obesity
3. Cognitive impairment
4. Chronic sepsis
5. Poorly controlled blood pressure (greater than 150/90 mmHg), despite use of four agents
6. Overt congestive heart failure

Date of first enrolment

30/04/2002

Date of final enrolment

30/07/2006

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Renal Unit

London

United Kingdom

E1 1BB

Sponsor information

Organisation

Barts and the London NHS Trust (UK)

ROR

<https://ror.org/00b31g692>

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	01/09/2009		Yes	No