ISRCTN17109689 https://doi.org/10.1186/ISRCTN17109689

Correction of acidosis in chronic kidney disease (CKD)

Submission date	Recruitment status	[_] Prospectively registered
03/12/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/01/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
04/07/2011	Urological and Genital Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Muhammad Magdi Yaqoob

Contact details
Renal Unit
Royal London Hospital
Whitechapel
London
United Kingdom
E1 1BB

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Primary end points are measured every three months.

Secondary outcome measures
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.

Overall study start date
30/04/2002

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
134

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
England

United Kingdom

Study participating centre
Renal Unit
London
United Kingdom
E1 1BB

Sponsor information

Organisation
Barts and the London NHS Trust (UK)

Sponsor details
c/o Gerry Leanord
Research and Development Directorate
Whitechapel
London
England
United Kingdom
E1 1BB

Sponsor type
Hospital/treatment centre

Website
http://www.bartsandthelondon.org.uk/

ROR
https://ror.org/00b31g692

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	01/09/2009		Yes	No