

Correction of metabolic acidosis in continuous ambulatory peritoneal dialysis patients with borderline dialysis adequacy - effect on nutritional status, systemic inflammatory response and patient morbidity

Submission date 10/10/2002	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 10/10/2002	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 02/07/2009	Condition category Nutritional, Metabolic, Endocrine	<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

Contact name
Dr CC Szeto

Contact details
Department of Medicine & Therapeutics
Prince of Wales Hospital
Chinese University of Hong Kong
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Hong Kong
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

931010

Study information

Scientific Title

Study objectives

Evaluate the effects of correcting acidosis by oral sodium bicarbonate in peritoneal dialysis patients with weekly Kt/V values below 2.1.

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)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Metabolic acidosis

Interventions

Patients will be randomised to receive either:

1. Oral sodium bicarbonate 0.9 g three times a day (tds)
2. Placebo

Patients were followed up for 12 months.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Sodium bicarbonate

Primary outcome measure

1. Nutritional status
2. Total number of days in hospital admission during study period
3. All-cause mortality

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/12/2000

Completion date

01/04/2003

Eligibility**Key inclusion criteria**

1. End-stage renal failure patients
2. Receiving Continuous Ambulatory Peritoneal Dialysis (CAPD)
3. Weekly Kt/V 1.6 to 1.9
4. Metabolic acidosis (plasma bicarbonate less than 24 mmol/l)

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

60

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

01/12/2000

Date of final enrolment

01/04/2003

Locations**Countries of recruitment**

Hong Kong

Study participating centre
Department of Medicine & Therapeutics

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Hong Kong

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Sponsor information

Organisation

Hong Kong Health Services Research Fund (Hong Kong)

Sponsor details

Health Welfare and Food Bureau
Government Secretariat, HKSAR
20th floor Murray Building
Garden Road

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Hong Kong

-

+852 (0)2973 8288
hsrf@hwfb.gov.hk

Sponsor type

Government

Website

http://www.fhb.gov.hk/grants/english/funds/funds_hhsrf/funds_hhsrf_abt/funds_hhsrf_abt.html

ROR

<https://ror.org/03qh32912>

Funder(s)

Funder type

Government

Funder Name

Hong Kong Health Services Research Fund (Hong Kong)

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	01/08/2003		Yes	No