ISRCTN35726272 https://doi.org/10.1186/ISRCTN35726272

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	Recruitment status
10/10/2002	No longer recruiting
Registration date	**Overall study status**
10/10/2002	Completed
Last Edited	**Condition category**
02/07/2009	Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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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
-
Hong Kong
-

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
-
Hong Kong
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+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