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Decreased salivary flow rate as a dipsogenic factor in haemodialysis patients: a pilocarpine clinical trial

Submission date	Recruitment status	[_] Prospectively registered
30/03/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/04/2005	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
15/02/2008	Urological and Genital Diseases	[_] Record updated in last year

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
N/A

Study information

Scientific Title

Study objectives
We conducted a 3-month prospective observational study followed by a trial of pilocarpine - a parasympathomimetic agent shown to effectively increase salivary flow in radiation-induced xerostomia or Sjögren syndrome (27 - 30) - to determine whether the reduction of salivary flow contributes to exaggerated thirst and excess interdialytic weight gain (IDWG) in haemodialysis (HD) patients, and whether pilocarpine can alleviate it.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study protocol was approved by ethics committees of National Cheng Kung University Hospital and Kuos General Hospital, Tainan, Taiwan, and adhered to the Declaration of Helsinki.

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
Haemodialysis (HD) patient with large weight gain (>2%/day)

Interventions
5 mg pilocarpine OPD solution (1% pilocarpine HCl ophthalmic solution, Shionogi & Co., Taipei, Taiwan) was used. The placebo was constructed using normal saline and Mill-Q water with 3:7 mixing. The sodium concentration of the two solutions was identical, with both administered in fixed doses (10 drops four times/day, 30 minutes before each meal and at bed time). Ten drops of pilocarpine is equivalent to 5 mg.

Intervention Type
Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)
Pilocarpine

Primary outcome measure
The primary outcomes were:
1. Changes in the visual analogue scale (VAS) scores of xerostomia, thirst, and stress of fluid restriction
2. Unstimulated salivary flow rate (UWS)
3. Mean IDWG2days and IDWG3days in each intervention period

Secondary outcome measures
The secondary outcomes were:
1. Changes in mean blood pressure
2. Adverse events
3. Blood test results

Overall study start date
01/03/2003

Completion date
31/10/2003

Eligibility

Key inclusion criteria
In the observational study, we collected prospective data for 3 consecutive months (December 2002 to February 2003) from 90 participants recruited from a pool of 217 patients undergoing HD at the outpatient dialysis unit of the Kuo's General Hospital. Inclusion criteria included:
1. Maintenance HD three times weekly for at least 6 months
2. Over 18 years of age
3. Daily urine output less than 200 ml
4. Stable clinical condition with stable dry weight and hematocrit

The inclusion and exclusion criteria for the intervention study (March to October 2003), were the same as those for the observation study except that:
5. Only hyperdipsic patients (IDWG % greater than 2%/day) were included
6. Patients using the xerogenic mediations were included if these drugs could be stopped at least 14 days before entering and throughout the interventional study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Haemodynamic instability preventing sufficient ultrafiltration
2. Hospitalisation within the preceding 3 months
3. Dementia or terminal diseases
4. Those not feasible to investigate for logistic reasons
5. Depression or anxiety (which cause xerostomia possibly due to the dysfunction of both brain and salivary glands)
6. Using xerogenic mediations (including anticholinergies, antidepressants, antipsychotics, antihistamines, antiparkinsonian agents, and diuretics)
7. Unwilling to participate in this study

Date of first enrolment
01/03/2003

Date of final enrolment
31/10/2003

Locations

Countries of recruitment
Taiwan

Study participating centre
138 Shing-Li Road
Tainan
Taiwan
70428

Sponsor information

Organisation
National Cheng Kung University (Taiwan)

Sponsor details
138 Shing-Li Road
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70428

Sponsor type
University/education

Website
http://www.ncku.edu.tw/en/

ROR
https://ror.org/01b8kcc49

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Cheng Kung University Hospital Research Committee (Taiwan) - research grants (ref: NCKUH-2003-05 and NCKUH-2004-63)

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