

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

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<b>Registration date</b> 19/04/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 15/02/2008	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

### Protocol serial number

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

## **Study type(s)**

Treatment

## **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(s)**

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

## **Key secondary outcome(s))**

The secondary outcomes were:

1. Changes in mean blood pressure
2. Adverse events
3. Blood test results

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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 anticholinergics, 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)

**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**

**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration