

# Dulaglutide for peritoneal dialysis in diabetic kidney disease

<b>Submission date</b> 19/10/2022	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 26/10/2022	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Protocol
<b>Last Edited</b> 24/10/2022	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<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

### Background and study aims

Taiwan has the highest rate of end-stage kidney disease or kidney failure in the world. Co-existing disease, inadequate dialysis and uremic solutes accumulate are the serious risk factors for death in patients with end-stage kidney disease. Renal replacement therapy is a therapy for patients with kidney failure that replaces kidney function. It includes hemodialysis, peritoneal dialysis, and kidney transplant. Unlike haemodialysis, an advantage of peritoneal dialysis is that it can be done at home/work without assistance, and it is better than haemodialysis to patients on maintenance dialysis. However, inadequate dialysis is the common fate in diabetic patients who receive peritoneal dialysis

Previously, we have demonstrated that gut hormones-based treatment [i.e., dipeptidyl peptidase-4 (DPP-4) inhibitors or glucagon-like peptide 1 (GLP-1) agonist] increased in GLP-1 levels, in further saved the peritoneal function from peritoneal fibrosis (scar tissue) in animal study. Currently, there remains a lack of effective method for recovering the function of peritoneum in peritoneal dialysis patients. Therefore, to confirm the effectiveness of GLP1 agonist on "early prevention" of peritoneal dialysis failure is very important. The current study will test whether dulaglutide treatment will maintain the structural and functional integrity of the peritoneal membrane in peritoneal dialysis.

### Who can participate?

Diabetic PD patients aged 20 - 75 years, who started PD over 3 months previously

### What does the study involve?

The patients will be randomly allocated into treatment group (dulaglutide/0.75mg adjust to 1.5 mg/QW; n=30) and control group (standardized pharmacotherapy only; n=30).

### What are the possible benefits and risks of participating?

#### Potential benefits:

1. They may get a new treatment for a disease before it is available to everyone.
2. They play a more active role in their own health care.
3. Doctors and other health professionals may provide them with medical care and more frequent health check-ups as part of their treatment.

4. The study may help reduce the incidences of ultrafiltration failure and peritoneal dialysis failure, and peritonitis rate.

Potential risks:

1. There may be minor discomfort, or side effects to experimental treatment.
2. The study may require more time and attention than standard treatment would, including visits to the study site, more urine/blood tests, more treatments, or complex dosage schedules.

Where is the study run from?

Kaohsiung Chang Gung Memorial Hospital (Taiwan)

When is the study starting and how long is it expected to run for?

January 2021 to December 2026

Who is funding the study?

Kaohsiung Chang Gung Memorial Hospital (Taiwan)

National Science and Technology Council (Taiwan)

Who is the main contact?

Dr Hon-Kan Yip, [han.gung@msa.hinet.net](mailto:han.gung@msa.hinet.net)

## Contact information

**Type(s)**

Public

**Contact name**

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## Additional identifiers

**Clinical Trials Information System (CTIS)**

Nil known

**Protocol serial number**

Nil known

## Study information

**Scientific Title**

To investigate the therapeutic impact of dulaglutide on preventing peritoneal dialysis dysfunction: a randomized, open-Label, controlled clinical trial and animal model

**Study objectives**

Dulaglutide may preserve the kidney functional integrity in diabetic kidney disease patient with peritoneal dialysis

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 23/09/2021, Chang Gung Medical Foundation IRB (No. 199, Dunhua N. Rd., Songshan Dist., Taipei City 105406, Taiwan (R.O.C.); +886-3-3196200 ext.3705; tsengshui@cgmh.org.tw), ref: 202101696A3

**Study design**

Prospective single center interventional trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Diabetes and peritoneal dialysis

**Interventions**

We will prospectively and consecutively enroll the diabetic peritoneal dialysis patients (n=60) to participate this clinical trial. Study subjects will be randomly allocated by sealed envelope into the treatment group (dulaglutide/0.75 mg adjust to 1.5 mg/QW; n=30) and the control group (standardized pharmacotherapy, including antihyperglycemic medicines; n=30).

The dulaglutide therapy will be maintained for one year, and the patients will be followed up for one year to answer the primary and secondary endpoints.

**Intervention Type**

Drug

**Phase**

Phase I

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

Dulaglutide

**Primary outcome(s)**

1. Change from Baseline in the Mean Peritoneal Fluid Glucose ratio (D4/D0) after 12 Months of Treatment with Dulaglutide.

[Time Frame: baseline, 6 months and 12 months]

The mean glucose concentrations will be evaluated by the Peritoneal Equilibrium Test from

Baseline and after 6 and 12 months with Dulaglutide treatment. The peritoneal equilibration test (PET) characterizes the peritoneal transport of fluid, creatinine and urea using a 4.5% dextrose peritoneal fluid. The concentration of glucose in the dialysis fluid (D4) at 4 hours is divided by the glucose in the dialysis fluid at the beginning (D0), generating the D4/D0.

2. Change from Baseline in the Mean Ultrafiltration Volume after 12 Months of Treatment with Dulaglutide.

[Time Frame: baseline, 6 months and 12 months]

Ultrafiltration volume from Baseline and after 6 and 12 months with Dulaglutide treatment assessment by the Peritoneal Equilibrium Test. The modified peritoneal equilibration test (PET) characterizes the peritoneal transport of fluid, creatinine and urea using a 4.5% dextrose peritoneal fluid.

3. Change from Baseline in the Mean 4 Hour Peritoneal Fluid to Plasma Creatinine (D/P) after 12 Months of Treatment with Dulaglutide.

[Time Frame: baseline, 6 months and 12 months]

The peritoneal equilibration test (PET) characterizes the peritoneal transport of fluid, creatinine and urea using a 4.5% dextrose peritoneal fluid. The concentration of creatinine in the dialysis fluid (D) at 4 hours is divided by the plasma creatinine (P), generating the D/P creatinine.

4. Change from Baseline in the Mean 4 Hour Peritoneal Fluid to Plasma BUN (D/P) after 12 Months of Treatment with Dulaglutide.

[Time Frame: baseline, 6 months and 12 months]

The peritoneal equilibration test (PET) characterizes the peritoneal transport of fluid, creatinine and urea using a 4.5% dextrose peritoneal fluid. The concentration of creatinine in the dialysis fluid (D) at 4 hours is divided by the plasma BUN (P), generating the D/P BUN.

5. According to D/P creatinine, peritoneal transport status was categorized as low (L), low average (LA), high average (HA) and high (H) ( $L < 0.5$ ,  $LA 0.5-0.64$ ,  $HA 0.65-0.80$ ,  $H \geq 0.81$ ).

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

[Time frame: baseline (pre-treatment), and 12 months (post-treatment)].

1. Incidence rate of ultrafiltration failure measured using patient records
2. Incidence rate of peritoneal dialysis failure (i.e., peritoneal dialysis transfer to hemodialysis)
3. Incidence rate of peritonitis measured using patient records
4. Preservation of residual renal function in dialysis patients (i.e., 24-hour urinary urea and creatinine clearance and urine total protein to creatinine ratio)

### **Completion date**

31/12/2026

## **Eligibility**

### **Key inclusion criteria**

1. CKD with a clinical cause of diabetes mellitus
2. Age is  $\geq 20$  and  $\leq 75$  years
3. The subject had been receiving peritoneal dialysis for more than 3 months.
4. The subject treat with or without OHAs or insulin treatment
5. The subject doesn't treated with GLP-1 analogue
6. The subject is able and willing to return for required follow-up visits and examinations.

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

20 years

**Upper age limit**

75 years

**Sex**

All

**Key exclusion criteria**

1. Female participants who are pregnant or breastfeeding
2. Participants who have any of the following medical conditions:
  - 2.1. Chronic inflammatory or autoimmune diseases
  - 2.2. Viral Hepatitis B or C liver infection, liver cirrhosis, or significant liver disease
  - 2.3. CKD from causes other than diabetes
  - 2.4. Cancer (malignancy)
  - 2.5. Febrile illnesses
  - 2.6. Age is < 20 or >75 years
  - 2.7. The subject has a life expectancy of less than one years.
  - 2.8. The subject has allergic reaction to any GLP-1 analogues.
  - 2.9. HIV infection- the virus that causes AIDS
  - 2.10. The subject is deemed by study physicians to be unsuitable for enrollment.
  - 2.11. The subject is currently enrolled in another investigational study or registry that would directly/indirectly interfere with the current study.
  - 2.12. The subject is unable or unwilling to return for required follow-up and examination.

**Date of first enrolment**

01/01/2022

**Date of final enrolment**

31/12/2025

**Locations**

**Countries of recruitment**

Taiwan

**Study participating centre**

**Kaohsiung Chang Gung Memorial Hospital**

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## Sponsor information

### Organisation

Chang Gung Memorial Hospital

### ROR

<https://ror.org/02verss31>

## Funder(s)

### Funder type

Hospital/treatment centre

### Funder Name

Kaohsiung Chang Gung Memorial Hospital

### Alternative Name(s)

Kaohsiung CGMH

### Funding Body Type

Private sector organisation

### Funding Body Subtype

Other non-profit organizations

### Location

Taiwan

### Funder Name

National Science and Technology Council

### Alternative Name(s)

National Science and Technology Council of Zambia, NSTC

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

### Location

Zambia

## Results and Publications

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

The data-sharing plans for the current study are unknown and will be made available at a later date.

### **IPD sharing plan summary**

Data sharing statement to be made available at a later date