# Assessment of the safety of a cell-based therapy on reducing the deterioration of kidney function in patients with kidney disease

Recruitment status  No longer recruiting	<ul><li>Prospectively registered</li></ul>		
	☐ Protocol		
Overall study status Completed	Statistical analysis plan		
	[X] Results		
Condition category	Individual participant data		
	No longer recruiting  Overall study status  Completed		

# Plain English summary of protocol

Background and study aims

The prevalence and incidence of chronic kidney disease (CKD), a long-term disease in which the kidneys do not work effectively, in Taiwan are much higher than in other countries. The incidence of end-stage renal disease (ESRD), when the kidneys stop working properly for an individual to live without dialysis or a transplant, in Taiwan is the highest in the world. The advances in drug treatments might slow the deterioration of the kidney function, but cannot reverse or cure the progression of CKD. Since patients who have CKD have poor responses to medications for the prevention of kidney function deterioration, stem cell therapy might be an alternative choice for them. The aim in this study is to assess the safety of this therapy on reducing the deterioration of kidney function in patients with CKD.

Who can participate?

Patients 20–80 years old, with chronic kidney disease due to increased blood pressure (hypertension)

What does the study involve?

Endothelial progenitor cells will be injected in the right artery of the kidney

What are the possible benefits and risks of participating?

The benefit is an improvement in renal function. The risks are bleeding, haematoma, contrast-induced nephropathy, malignancy, pain, sepsis, and artery dissection.

Where is the study run from?

Chang Gung Memorial Hospital (Taiwan).

When is the study starting and how long is it expected to run for? From August 2014 to July 2017

Who is funding the study?
Chang Gung Memorial Hospital (Taiwan)

Who is the main contact? Dr Hon-Kan Yip han.gung@msa.hinet.net

# Contact information

# Type(s)

**Public** 

#### Contact name

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# Additional identifiers

**Protocol serial number** N/A

# Study information

#### Scientific Title

Therapeutic potential of CD34+ endothelial progenitor cell therapy on attenuating the deterioration of kidney function in patients with chronic kidney disease: a safety analysis

## **Study objectives**

The prognosis of patients with chronic kidney disease (CKD) and other co-morbidities, like sepsis, coronary artery disease, heart failure with pulmonary oedema, are worse than those without CKD, and the mortality rate in patients with CKD are also very high during hospitalisation. Finding a new, effective and safe strategic management is of the utmost importance for patients, nephrologists and physicians and is important to reduce the medical costs in Taiwan. The causes of CKD are divergent and varied, including hypertension, diabetes mellitus and dyslipidaemia, and they initiate endothelial cell dysfunction and propagation of obstructive atherosclerosis. Additionally, inadequate use of drugs might also cause progressive loss of the renal microvasculature, which leads to hypoxia in local tissue and induction of fibrotic responses, scarring and deterioration of renal function.

Results from experimental studies have shown that stem cell therapy improves ischaemiarelated organ dysfunction. Also, many clinical trials have shown that both endothelial progenitor cells (EPCs) and mesenchymal stem cells (MSCs), which are derived from bone marrow, peripheral blood or adipose tissue, significantly improve left ventricular function in acute myocardial infarction or chronic ischaemic heart disease. In human studies, the number and function of EPCs decrease significantly in patients with CKD. Studies of animal models have shown stem cell therapy restores renal function in chronic CKD. No data have been reported for human CKD.

Hypothesis: CD34+ endothelial progenitor cell therapy can safely attenuate the deterioration of kidney function in patients with CKD.

## Ethics approval required

Old ethics approval format

### Ethics approval(s)

Chang Gung Memorial Hospital, 24/09/2014, 102-0358A

#### Study design

Interventional single-arm single-centre trial

#### Primary study design

Interventional

## Study type(s)

Treatment

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

Chronic kidney disease

#### **Interventions**

Intrarenal artery infusion of CD34+ endothelial progenitor cells

# Intervention Type

Biological/Vaccine

### Primary outcome(s)

Percentage of patients with an improvement of 5 mL/min in creatinine clearance rate after CD34+ cell treatment at baseline and at 1 week, 1 months, 6 months, 9 months and 12 months after therapy

# Key secondary outcome(s))

Significant reductions in:

- 1. Proteinuria, will be measured every day after therapy for 3 days
- 2. Creatinine, will be measured every day after therapy for 3 days
- 3. Combined secondary end-point, defined as acute renal failure with requirement for haemodialysis, or death, at 1 week, 1 month, 3 months, 6 months, 9 months and 12 months after therapy

# Completion date

31/07/2017

# **Eligibility**

# Key inclusion criteria

- 1. Age 20–80 years old
- 2. Chronic kidney disease due to hypertension after optimum drug therapy
- 3. Chronic kidney disease, stage III–IV with stable renal function within 1 year

# Participant type(s)

Patient

## Healthy volunteers allowed

No

#### Age group

Adult

#### Sex

All

#### Total final enrolment

10

#### Key exclusion criteria

- 1. Younger than 20 years old or older than 80 years old
- 2. Pregnant or breastfeeding women
- 3. Infections (e.g., with human immunodeficiency virus [HIV])
- 4. Myocardial infarction or congestive heart failure (functional class IV) within 3 months
- 5. Malignancy
- 6. Other severe organ failure
- 7. Life expectancy of less than 1 year
- 8. End-stage renal disease

#### Date of first enrolment

24/09/2014

#### Date of final enrolment

31/05/2016

# Locations

#### Countries of recruitment

Taiwan

# Study participating centre Chang Gung Memorial Hospital

123 Ta Pei Road Niao Sung District Kaohsiung Taiwan 833

# Sponsor information

# Organisation

Chang Gung Memorial Hospital

#### **ROR**

https://ror.org/02verss31

# Funder(s)

# Funder type

Hospital/treatment centre

#### **Funder Name**

Chang Gung Memorial Hospital (Taiwan)

# **Results and Publications**

# Individual participant data (IPD) sharing plan

Not provided at time of registration

# 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		14/03/2017	15/02/2022	Yes	No