

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

Submission date 20/01/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 24/02/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 15/02/2022	Condition category Urological and Genital Diseases	<input type="checkbox"/> Individual participant data

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?
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Contact information

Type(s)

Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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 ischaemia-related 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

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 measure

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 month, 3 months, 6 months, 9 months and 12 months after therapy

Secondary outcome measures

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

Overall study start date

01/08/2014

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

Age group

Adult

Sex

Both

Target number of participants

10

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

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Taiwan

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Sponsor information

Organisation

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Sponsor type

Hospital/treatment centre

ROR

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

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Results and Publications

Publication and dissemination plan

We will publish and disseminate our study results before 31/12/2017.

Intention to publish date

31/12/2017

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