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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

Registration date
24/02/2015

Overall study status
Completed

Last Edited
15/02/2022

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
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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