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Application of peripheral blood-derived stem cell (CD34) therapy on chronic kidney disease

Submission date
30/07/2018

Recruitment status
No longer recruiting

Registration date
22/08/2018

Overall study status
Completed

Last Edited
11/08/2022

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
Chronic kidney disease (CKD) is a long-term disease in which the kidneys do not function effectively. The incidence of CKD is much higher in Taiwan than in other countries. End-stage CKD is where almost all kidney function is lost and patients have to rely on dialysis to remove waste products from the blood. Various drugs can be used to slow down deterioration of kidney function, but cannot reverse or cure the progression of CKD. Additionally, patients with CKD can have poor responses to these treatments. An alternative is stem cell therapy, where stem cells (cells capable of developing into other types of cell) to replace damaged kidney cells. The aim of this study is to look at the efficacy of stem cell therapy for reducing the deterioration of kidney function in patients with CKD.

Who can participate?
Patients aged 20-80 years with chronic kidney disease

What does the study involve?
The participants are randomly allocated to one of two groups, either the study group or the control group. The study group will receive standard medication for CKD, along with stem cell therapy, whereas the control group will receive standard medication only.es standard medical therapy. All participants will receive 1 year of follow-up to assess their kidney function.

What are the possible benefits and risks of participating?
The possible benefit of participating is that participants may have improved kidney function as a result. The possible risks of participating are haematoma, contrast-induced nephropathy, malignancy, pain, sepsis and artery dissection.

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 2016 to December 2020

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

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
TFDA No. 105IND04085

Study information

Scientific Title
Application of peripheral blood-derived stem cell/progenitor cell (CD34) therapy on chronic kidney disease: Phase 2 clinical trial

Study objectives
The peripheral blood-derived stem cell/progenitor cell (CD34) may be a therapeutic option for patients with chronic kidney disease

Ethics approval required
Old ethics approval format

Ethics approval(s)
Chang Gung Memorial Hospital No. 201600371A0, 19/05/2016, 201600371A0
Taiwan FDA, 23/08/2016, 105IND04085

Study design

Interventional prospective single-center randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Chronic kidney disease

Interventions
Participants will be evenly divided into the intervention group and the controlled group using the envelope method.
Participants in the intervention group will receive standard medication for chronic kidney disease, along with the administration of blood-derived stem cell/progenitor cell (CD34) therapy, while the control group will receive only standard medication.
Standard medication includes angiotensin-converting-enzyme inhibitors (ACEI), angiotensin II receptor blockers (ARB), dopamine reuptake inhibitors (DRI), beta-blockers or calcium channel blockers (CCB) to maintain normal blood pressure within a range of less than 140/90 mmHg.
All participants will receive a 1 year follow up period, where participants will undergo blood biochemistry tests, renal ultrasounds and vital signs will be monitored at 1 week and 3, 6, 9 and 12 months after the intervention period.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Peripheral blood-derived stem cells/progenitor cells (CD34)

Primary outcome measure
Improvement of Ccr (creatinine clearance rate cc/min) from the baseline, assessed using serum creatine levels at the baseline, and after 1 week and 1, 3, 6, 9 and 12 months

Secondary outcome measures
1. Reduction of proteinuria value (albumin/creatinine ratio), assessed at the baseline, and after 1 week and 1, 3, 6, 9 and 12 months. The albumin concentration per creatine level in urea is assessed using the microalbumin test and the urine protein/creatinine ratio is assessed by the Urine Protein-Creatinine Ratio (UPCR) test.

2. Incidence of renal failure (either requiring haemodialysis or causing death) within the 1 year follow-up period

Overall study start date
31/01/2016

Completion date
31/12/2020

Eligibility

Key inclusion criteria
1. Aged 20-80 years old
2. Renal failure due to hypertension
3. Receiving optimal medical therapy (received optimal therapy for more than 12 weeks and have been evaluated by a nephrologist. Medication includes ACEI, ARB, DRI, beta-blocker or CCB. Blood pressure is less than 140/90 mmHg)
4. Renal function between chronic kidney disease (CKD) stage III-IV
5. Stable renal function maintained for 1 year before study (creatinine clearance rate between 15-60 ml/min and no significant changes)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
56 subjects (28 subjects for treatment group and 28 subjects for control group)

Total final enrolment
52

Key exclusion criteria
1. Pregnant or breastfeeding
2. Infected with HIV
3. Infected with HBV or HCV
4. Myocardial infarction within 3 months prior to study
5. Heart failure (functional class IV)
6. Malignant or hematological disease
7. Severe disease with lifespan less than 1 year
8. End stage renal disease
9. Creatinine clearance rate less than 15 ml/min
10. Kidney disease on only one side
11. Participating in other clinical trials

12. Unable to receive therapies used in this study
13. Organ transplantation
14. Autoimmune disease

Date of first enrolment
01/06/2016

Date of final enrolment
31/05/2019

Locations

Countries of recruitment
Taiwan

Study participating centre
Kaohsiung Chang Gung Memorial Hospital
No.123, Ta Pei Road, Niao Sung District
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Sponsor information

Organisation
Ministry of Science and Technology, Taiwan

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Funder(s)

Funder type
Not defined

Funder Name
Ministry of Science and Technology (105-2325-B-182A-002 -)

Funder Name
Chang Gung Medical Research Program Grant

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed journal in 2020

Intention to publish date
31/12/2020

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		16/04/2020	20/01/2022	Yes	No