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The effect of resistance training and aerobic exercise on vascular stiffness, novel cardiovascular risk markers, aerobic capacity, muscle strength and incidence of complications in the first year of renal transplantation. A randomised controlled study

Submission date
31/07/2014

Recruitment status
No longer recruiting

Registration date
31/07/2014

Overall study status
Completed

Last Edited
06/02/2017

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
13611

Study information

Scientific Title
The effect of resistance training and aerobic exercise on vascular stiffness, novel cardiovascular risk markers, aerobic capacity, muscle strength and incidence of complications in the first year of renal transplantation. A randomised controlled study

Acronym
ExeRT Trial (EXErcise in Renal Transplant Trial)

Study objectives
Physical activity and exercise plays a beneficial role in maintaining the health in those with chronic illnesses however poor physical functioning among patients with chronic kidney disease is well-recognised. The use of modern immunosuppressant therapies have improved the life-expectancy of kidney grafts, however, risks of secondary complications such as diabetes, cardiovascular disease and obesity are an associated risk. It has been established that recipients of kidney transplants increase their physical activity level in the subsequent years after transplantation due to improved quality of life; however within that time they do not reach the level of physical activity of those of age matched healthy controls. Regular aerobic exercise helps to prevent and treat cardiovascular disease and to prevent and reverse arterial stiffening. Resistance training is also an important physical activity that can prevent or treat lifestyle-related diseases. However, high-intensity resistance training reduces arterial compliance and increases arterial stiffness, although this is not a universal finding. That is, regular aerobic exercise increases, whereas high-intensity resistance training decreases arterial compliance. This project will examine the effect and timing of aerobic exercise and resistance training exercise delivered in a 24-week supervised outpatient class setting, on vascular stiffness, aerobic capacity, functional ability, transplant outcomes and quality of life in patients who have received a kidney transplant. The project aims to provide evidence for the importance of exercise for patients that have received a kidney transplant and encourage the commissioning of physiotherapy services for this patient group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
12/LO/1644

Study design
Randomised; Interventional; Design type: Not specified, Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Topic: Renal disorders; Subtopic: Renal disorders; Disease: All Renal disorders

Interventions
Aerobic training: AT will predominantly be on stationary exercise cycles at 80% hear rate reserve. Resistance Training: Resistance training will use RT machines training large muscle groups (e.g. bench press, latissimus pulldown, bicep curl, triceps pull down,leg press, knee extension, hamstring curl, calf raises). Intensity will be 80% of 1RM, building up to 3 sets of 10 reps.; Study Entry : Single Randomisation only

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Pulse Wave Velocity (PWV); Timepoint(s): Baseline, 12 weeks and 12 months

Secondary outcome measures
1. CVD biomarkers - Fetuin A, TNF receptor 2, IL6, HS CRP; Timepoint(s): Baseline, 12 weeks and 12 months
2. Duke's Activity Status Index; Timepoint(s): Baseline and 12 weeks
3. Muscle strength (myometer); Timepoint(s): baseline and 12 weeks
4. Resting heart rate and blood pressure; Timepoint(s): baseline, 12 weeks and 12 months
5. Sit to stand 60; Timepoint(s): baseline and 12 weeks
6. VO2peak; Timepoint(s): baseline, 12 weeks and 12 months

Overall study start date
01/03/2013

Completion date
31/10/2014

Eligibility

Key inclusion criteria
1. All patients undergoing renal transplant
2. Male or female

3. Aged >18 years
4. Written informed consent; Target Gender: Male & Female ; Lower Age Limit 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 60; UK Sample Size: 60

Key exclusion criteria
1. Requiring support for ambulation less than 20m
2. Vasculitis
3. Proliferative diabetic retinopathy,
4. Severe osteodystophy
5. Uncontrolled diabetes
6. Psychiatric illness, including anxiety, mood and untreated eating disorders
7. Infection or course of antibiotics within the last month

Date of first enrolment
01/03/2013

Date of final enrolment
31/10/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Denmark Hill
London
United Kingdom
SE5 9RS

Sponsor information

Organisation
King's College Hospital NHS Foundation Trust (UK)

Sponsor details
Dept of Research & Development KCH
34 Love Walk
London
England
United Kingdom
SE5 8AD

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01n0k5m85

Funder(s)

Funder type
Government

Funder Name
NIHR Doctoral Research Fellowship; Grant Codes: NIHR-DRF-2012-05-874

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

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	results	03/02/2017		Yes	No
HRA research summary			28/06/2023	No	No