

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	<input type="checkbox"/> Prospectively registered
Registration date 31/07/2014	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 06/02/2017	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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 osteodystrophy
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