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Airogym exercise on solute removal

Submission date	Recruitment status	[_] Prospectively registered
11/08/2016	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/09/2016	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
15/09/2016	Urological and Genital Diseases	[_] Record updated in last year

Plain English summary of protocol

Background & Study aims
Kidney dialysis is a medical procedure that removes waste products and excess fluid from the blood in people whose kidneys have stopped working properly, namely patients with chronic kidney disease (CKD) or end stage kidney failure. The procedure is expensive and there is limited availability of these sorts of expensive therapies in the majority of emerging countries and more so in African nations. The aim of this study is to find out whether exercise during haemodialysis (the most common type of kidney dialysis) has an effect on solute (i.e. waste product) removal from the blood and to identify whether there are any other possible benefits such as preventing deep vein thrombosis, improvement in blood circulation and reduction in swelling and edema (build-up of fluid in the tissues).

Who can participate?
End stage kidney disease patients aged between 30-50 years.

What does the study involve?
This study is called a Quasi-experimental investigation, since patients participating in study know whether they are in the intervention (test) group or the control group. They are randomly allocated to one of the groups. Patients in the intervention group exercise for fifteen minutes every hour using a Airogym exercise cushion. They exercise for a total of sixty minutes during each four-hour hemodialysis session. Patients in the control group do not have to exercise during their 4 hour hemodialysis sessions. Blood is taken from all patients in both groups once a month before and after the session. They are also all encouraged to exercise regularly, eat a healthy diet, get involved in social activities and attend psychological counselling (if necessary) to maintain their quality of life during the study.

What are the possible benefits and risks of participating?
No benefits are expected for the participants, but this study will improve the future treatment of end-stage kidney disease patients. There is no additional risk involved in this study.

Where is the study run from?
1. Newcastle Private Hospital Renal unit (South Africa)
2. Mediclinic Bloemfontein (South Africa)

Who is funding the study?
Durban University of Technology, Durban (South Africa)

Who is the main contact?
Professor Jamila Khatoon Adam

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
4426

Study information

Scientific Title
Effect of exercise on solute removal and edema on end stage renal disease patients

Acronym
Airogym exercise

Study objectives
1. Patients participating in the intervention group will show marked reduction in edema compared to the control group during a nine- month period of study
2. Patients participating in the intervention group will show a marked increase in solute removal compared to patients in the control group

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Research Ethics Committee, Durban University of Technology, 30/08/2006

Study design
Unblinded randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

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

Health condition(s) or problem(s) studied
Renal artery obstruction

Interventions
Between September 2006 to December 2006, 34 end stage renal patients for the study were recruited from two MediClinic Hospital Renal Units (namely, Newcastle Private Hospital Renal Unit and Bloemfontein MediClinic Renal Units, South Africa) where they have been on maintenance hemodialysis for at least 3 months.

Participants are randomly allocated to one of two groups.
1. The intervention group: this group exercised on a Airogym exercise cushion for 15 minutes every hour over a 4 hour dialysis session. They exercise for a total of 60 minutes over the 4 hour period.
2. The control group: this group do not have to exercise during their 4 hour dialysis session.

During the first three months of this study patients in the intervention group did not exercise on the exercise cushion (Airogym) to establish a baseline. Thereafter, from the fourth month until the ninth month patients in the intervention group pedalled on the exercise cushion during hemodialysis. All patients exercised at a slow steady rate to target a heart rate of 100 beats per minute and then slowed down gradually. A total of sixty minutes of exercise was performed over the four hours on hemodialysis. Urea, creatinine and potassium were quantitatively measured using standard laboratory techniques from patients (pre and post hemodialysis). Edema of the lower limb was measured in centimeters around the ankles (right and left) before and after dialysis.

Randomisation Method: Random allocation will be utilised to assign the patients to their respective groups, with the patients drawing a letter (A or B) out of an envelope. A total of twenty patients will be recruited from Bloemfontein (ten in group A and ten in group B) and fourteen from Newcastle (seven in group A and seven in group B)

Follow up of patients: On completion of the study, the patients recruited continued on chronic dialysis programme as was recommended by the nephrologist.

The Airogym:
The Airogym was designed specifically to address two common problems associated with long haul flying, i.e., ankle swelling and blood clotting. Patients with end-stage renal disease on haemodialysis are generally more prone to developing deep vein thrombosis, swelling and oedema due to having chronic renal failure. They often feel fatigued and are unable to join an exercise programme at the gymnasium or do any strenuous activities. This inactivity further increases the risk of developing deep vein thrombosis, swelling and oedema due to poor blood circulation. Both can be attributed to stagnation of the circulation. Anybody sitting or standing for long periods of time will notice ankle swelling and pain in the lower legs. Fortunately in the majority of passengers the clots dissolve without causing any apparent symptoms or signs, and leaving no long- term damage. On occasion the blood clot can grow and then a segment can break off and travel to the lungs. There are two problems associated with blood clots, one a clot in the lung, the other an effect which may take many years to manifest itself, namely the development of the post thrombotic limb. The airogym was designed specifically to promote the flow of blood through the deep veins. By pressing down on the footpad, veins in the foot are compressed, squeezing blood into the main veins in the calf. The pressure involved in squeezing the foot causes muscular contractions of the calf muscles promoting the flow of blood through the main veins. Results showed an improvement in peak velocity blood flow up to five times. The device prevented venous stasis and reduced the risk of developing blood clots and also prevented ankle swelling.

Intervention Type
Device

Primary outcome measure
Patients experience of the exercise program, measured using questionnaires completed once a month over a nine month period.

Secondary outcome measures
1. Urea, creatinine and potassium levels, measured using biochemical analysis of blood samples, taken once a month for nine months from each participant before the dialysis session and afterwards
2. Degree of edema of the lower limb, measured in centimeters around the ankles (right and left) before and after dialysis
3. Statistical Analysis. Paired student’s t-test was used to determine level of significance, using the statistical package SPSS 9.0 for Windows

Overall study start date
10/01/2006

Completion date
30/09/2007

Eligibility

Key inclusion criteria
1. On a chronic hemodialysis schedule
2. Hemodynamically stable
3. Attending haemodialysis at the Bloemfontein Mediclinic Hospital or Newcastle Private Hospital Renal Unit
4. Receiving haemodialysis twice or three times a week
5. Eighteen years old and above

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
34

Key exclusion criteria
1. Patients not on a chronic haemodialysis schedule
2. Patients medically unfit to participate (confirmed by doctor’s incharge of renal unit patients)
3. Patients not willing to comply with protocol
4. Patients that are diabetic

Date of first enrolment
20/09/2006

Date of final enrolment
30/12/2006

Locations

Countries of recruitment
South Africa

Study participating centre
Newcastle Private Hospital Renal unit
Hospital St, Newcastle
Durban
South Africa
2940

Study participating centre
Mediclinic Bloemfontein
Cnr Kellner & Parfitt Street
Westdene
Bloemfontein, Free State
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9301

Sponsor information

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ROR
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Funder(s)

Funder type
University/education

Funder Name
Durban University of Technology

Results and Publications

Publication and dissemination plan

The outcome of the research study will be published in International Medical Journals in 2016.

Intention to publish date
01/12/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available