

The effects of strength training and protein intake in patients undergoing dialysis

Submission date 14/04/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 28/04/2011	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 13/02/2015	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

Protocol serial number
N/A

Study information

Scientific Title
The effects of 16 weeks high load strength training and protein intake in patients undergoing dialysis: a prospective randomised controlled trial

Study objectives
Strength training and protein intake increase muscle strength more than strength training alone in patients undergoing dialysis

Ethics approval required

Old ethics approval format

Ethics approval(s)

Scientific committee, Region Hovedstaden, Denmark approved on 7th April 2009 (Number: H-D-2008-124)

Study design

Prospective randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Uremic myopathy in end-stage renal disease patients undergoing dialysis

Interventions

Exercise and intake of protein or non-protein energy:

Strength training for lower limbs three times per week in 16 weeks (48 sessions). The patients were randomised to exercise and a protein intake after each exercise session or exercise and a isocaloric non-protein intake.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

1. Muscle strength (equipment: Good Strength)
2. Muscle power (equipment: Power Rig)
3. Physical function (Chair stand test from The Senior Fitness Test)
4. Self-rated health (Short Form 36 questionnaire)
5. Muscle size and type (muscle biopsy from the vastus lateralis muscle)
6. Electromyography (EMG) (surface from the vastus lateralis muscle)
7. Anabolic hormones (blood tests)
8. Insulin resistance (the oral glucose tolerance test)

All tests are done three times: A pretest 16 weeks before the baseline test with no intervention in between and a final retest after the 16 weeks of intervention

Key secondary outcome(s)

1. Physical activity
2. Food intake
3. Body weight
4. Kidney function

All tests are done three times: A pretest 16 weeks before the baseline test with no intervention in between and a final retest after the 16 weeks of intervention

Completion date

31/12/2011

Eligibility

Key inclusion criteria

1. Age above 18 years
2. Dialysis more than three months
3. Able to do strength training
4. Able to talk and read Danish

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Blindness
2. Lower limb amputation
3. Diabetic retinopathy
4. Anticoagulation treatment by Fondaparinux (Arixtra®)
5. Mental reduction

Date of first enrolment

15/04/2009

Date of final enrolment

31/12/2011

Locations

Countries of recruitment

Denmark

Study participating centre

Solskrænten 6
Hillerød
Denmark
3400

Sponsor information

Organisation

University of Copenhagen (Denmark)

ROR

<https://ror.org/035b05819>

Funder(s)

Funder type

Other

Funder Name

Renal Association (Nyreforeningen) (Denmark)

Funder Name

Nutricia (Denmark)

Funder Name

Becket Fund (Becket-fonden) (Denmark)

Funder Name

Danish Society Nefrologisk (Dansk Nefrologisk Selskab) (Denmark)

Funder Name

Hillerød Hospitals Forskningspulje (Denmark)

Funder Name

Danske physiotherapy Research Foundation (Danske Fysioterapeuters Forskningsfond)
(Denmark)

Funder Name

Lundbeck Foundation (Lundbeckfonden) (Denmark)

Alternative Name(s)

Lundbeckfonden, The Lundbeck Foundation

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Denmark

Funder Name

Kaptajnløjtnant Harald Jensen and Wife Fund (Kaptajnløjtnant Harald Jensens og Hustrus fond)
(Denmark)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2013		Yes	No
Results article	results	01/03/2014		Yes	No