

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

<b>Submission date</b> 14/04/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 28/04/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 13/02/2015	<b>Condition category</b> 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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3400

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
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

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

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

**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 measure**

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

### **Secondary outcome measures**

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

### **Overall study start date**

15/04/2009

### **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

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Sex**

Both

### **Target number of participants**

42

**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)

**Sponsor details**

Faculty of Life Sciences (LIFE)

Bulowsvej 17

Frederiksberg C

Denmark

1870

**Sponsor type**

University/education

**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

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Other non-profit organizations

**Location**

Denmark

**Funder Name**

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

## 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?
<a href="#">Results article</a>	results	01/03/2013		Yes	No
<a href="#">Results article</a>	results	01/03/2014		Yes	No