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

Submission date	Recruitment status	[_] Prospectively registered
14/04/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
28/04/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
13/02/2015	Urological and Genital Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

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)

Primary study design
Interventional

Study design
Prospective randomised controlled trial

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. Selfrated health (Short Form 36 questionaire)
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 tolerence 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