

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

Submission date
14/04/2011

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
28/04/2011

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
13/02/2015

Condition category
Urological and Genital Diseases

☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr Stig Molsted

Contact details
Solskrænten 6
Hillerød
Denmark
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?
Results article	results	01/03/2013		Yes	No
Results article	results	01/03/2014		Yes	No