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Oral anabolic steroid increases muscle products in hemodialysis patients

Submission date
10/04/2012

Recruitment status
No longer recruiting

Registration date
16/04/2012

Overall study status
Completed

Last Edited
18/09/2014

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Protein-energy wasting is a common adverse consequence of end-stage kidney disease (ESKD) and is associated with impaired rehabilitation and increased morbidity (illness) and mortality (death). Individuals with ESKD are often poorly muscled. Moreover, low muscle mass in maintenance hemodialysis (MHD) patients is associated with increased mortality. Therapies designed to increase dialysis patients muscle mass and strength might therefore improve their exercise capacity and possibly their survival. Anabolic-androgenic steroid (AAS) therapy appears to be a promising alternative for treatment of muscle wasting in chronic illness. Anabolic steroids may increase lean body mass and muscle mass in adults without chronic kidney disease (CKD), as well as in MHD patients. Oxymetholone has the advantages that it can be given orally and exhibits higher anabolic activity and lower androgenic effects than testosterone. Several studies showed increased fat-free mass in patients taking oxymetholone, but no such studies have been conducted in people with CKD. The aim of this study is to examine whether orally administered oxymetholone improves protein-energy status and increases muscle mass in MHD patients.

Who can participate?
Patients aged 20 years or older, treated with MHD for at least 3 months.

What does the study involve?
Patients were randomly allocated to one of two treatment groups. One group received oxymetholone twice daily for 24 weeks. The other group received a placebo (dummy) drug in the same manner. All patients typically continued with their normal daily activities during both treatments and were monitored at home by a healthcare trainer. All patients kept a three-day food record and underwent dietary interviews by a registered dietitian. Body composition was assessed by dual energy absorptiometry on the day after a hemodialysis treatment, before and after the study period. Grip strength was also measured three times on each side, alternating between right and left hands using a handgrip dynamometer. Muscle biopsies of the right vastus lateralis muscle (on the side of the thigh) were performed at baseline and at the end of the study. Blood was collected immediately before a mid-week hemodialysis for biochemical

measurements every four weeks and at the end of the trial. Adverse events that were or were not considered to be related to oxymetholone treatment were monitored every four weeks. Patients also underwent blood drawing for safety tests.

What are the possible benefits and risks of participating?
Oxymetholone treatment might improve muscle metabolism, muscle mass and handgrip strength in MHD patients. In addition, the oxymetholone treatment may improve physical functioning and decrease fat mass. Previous studies demonstrated that oxymetholone increases the incidence of some side effects (e.g., absence of menstruation, hair loss, excess hair growth in women, and deepening voice), and slightly increases liver dysfunction.

Where is the study run from?
The Hemodialysis Unit of The Kidney Foundation of Thailand.

When is the study starting and how long is it expected to run for?
The study ran from January 2007 until January 2008.

Who is funding the study?
The National Research Council of Thailand.

Who is the main contact?
Dr Ouppatham Supasyndh
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Contact information

Type(s)
Scientific

Contact name
Dr Ouppatham Supasyndh

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Additional identifiers

Study information

Scientific Title
Oral anabolic steroid increases muscle products in hemodialysis patients: a randomized controlled trial

Study objectives
Orally administered oxymetholone can improve protein-energy status and increase muscle mass in maintenance hemodialysis patients

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institute Review Board Ethics Committee, Phramongkutklao Hospital, Thailand, January 2007, ref: S005h/49

Primary study design
Interventional

Study design
Randomized double-blind placebo-controlled study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Maintenance hemodialysis patients

Interventions
Eligible patients were randomly assigned into two groups. One group ingested oxymetholone, 50 mg twice daily for 24 weeks. The other group received a placebo in the same manner. All patients typically continued with their normal daily activities during both treatments and were monitored at home by a healthcare trainer.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Oxymetholone

Primary outcome(s)
1. Body composition was assessed by dual energy absorptiometry (DEXA; Hologic QDR-4500W, USA) on the day after a hemodialysis treatment, before and after the study period.
2. Grip strength was also measured three times on each side, alternating between right and left hands using a handgrip dynamometer
3. Muscle biopsies of the right vastus lateralis muscle were performed at baseline and at the end of the study. The muscle analyses include identification of mRNA levels by real-time polymerase chain reaction (PCR) amplification and protein concentrations of growth factors. Muscle fiber types were identified by nicotinamide dinucleotide diaphorase (NADH) staining and cross-sectional areas were examined by a renal pathologist. Blood was collected immediately before a mid-week hemodialysis for biochemical measurements, including testosterone, luteinizing hormone and cortisol at baseline, every 4 weeks and at the end of the trial.

Key secondary outcome(s)

Adverse events that were or were not considered to be related to oxymetholone treatment were monitored every 4 weeks. Patients also underwent blood drawing for safety tests that included complete blood counts, liver function tests and prostate-specific antigen.

Completion date
01/01/2008

Eligibility

Key inclusion criteria
1. Aged 20 years or older
2. Treatment with maintenance hemodialysis (MHD) for at least 3 months
3. A single pool Kt/Vurea of 1.2 or greater per MHD treatment
4. No treatment with androgens or glucocorticoids within 6 months before starting the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Patients with diabetes mellitus
2. Active malignancy
3. Severe heart, lung or liver disease, strokes, chronic infection (e.g., tuberculosis) within one year of starting the study
4. Any immunological or inflammatory disorders

Date of first enrolment
01/01/2007

Date of final enrolment
01/01/2008

Locations

Countries of recruitment
Thailand

Study participating centre

Division of Nephrology
Bangkok
Thailand
10400

Sponsor information

Organisation
The National Research Council of Thailand (Thailand)

ROR
https://ror.org/018wfhg78

Funder(s)

Funder type
Research council

Funder Name
The National Research Council of Thailand (Thailand), ref: 58519

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration