Harm reduction in anabolic androgenic steroid use

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To investigate:- Whether a harm reduction strategy with education and counseling is effective in reducing the use of AAS by amateur athletes. - The harm reduction potential of an additional online consultation with a well-known fitness expert. -...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON52267

Source
ToetsingOnline

Brief title
HARNAS-trial

Condition

- Other condition
- Hepatic and hepatobiliary disorders
- Respiratory disorders NEC

Synonym
androgen abuse, use of anabolic steroids

Health condition

middelenmisbruik, afhankelijkheid

Research involving
Human

Sponsors and support

Primary sponsor: Elisabeth-Tweesteden ziekenhuis
Source(s) of monetary or material Support: Dopingautoriteit

Intervention

Keyword: androgen abuse, bodybuilding, harm reduction, performance and image-enhancing drugs

Outcome measures

Primary outcome

• The effect of a harm reduction strategy on the duration of exposure to AAS by amateur athletes in a 12 month study period.

• The effect of a one-time online consultation about diet and training regimens on the duration of exposure to AAS in a 12 month study period.

• The extent to which providing a harm reduction intervention leads to a different amount of new users of AAS.

• The prevalence of obstructive sleep apnea syndrome during AAS use.

• The prevalence of non-alcoholic fatty liver disease during AAS use.

Secondary outcome

• The effect of a harm reduction strategy on the duration of growth hormone use and the number of times post-cycle therapy is employed in a 12 month study period.

• The extent to which the different user typologies predict the effectiveness of the harm reduction strategy..

• The incidence of serious adverse events during or after AAS use.

Study description

Background summary

The prevalence of anabolic androgenic steroid (AAS) use among men frequenting gyms is 4-6%. In the Netherlands an estimated 20.000 men use AAS. There is a lack of data about the negative health effects of AAS use, but current literature indicates that AAS increase cardiovascular risk, and disrupt endogenous testosterone production and spermatogenesis. The Center of Expertise for Anabolic Steroids in the Spaarne Gasthuis and Elisabeth-TweeSteden hospital in the Netherlands aims to provide more insight into the harmfulness of AAS use. In addition, medical care is provided to patients that experience health issues resulting from previous AAS use. Up till now, there is no primary or secondary prevention that has proved effective in reducing harm caused by AAS. Possibly there may be a role for medical experts in the field of AAS. As a harm reduction strategy they could provide users with advice and counseling.

Study objective

To investigate:
- Whether a harm reduction strategy with education and counseling is effective in reducing the use of AAS by amateur athletes.
- The harm reduction potential of an additional online consultation with a well-known fitness expert.
- Whether offering the entire harm reduction draws in more (new) users of AAS is also examined.
- The occurrence of sleep apneas and the obstructive sleep apnea syndrome during AAS use.
- The occurrence of non-alcoholic fatty liver disease during AAS use.

Study design

The HARNAS trial (harm reduction in anabolic androgenic steroid use) is a clinical intervention study with historical control group. A hundred male amateur athletes of at least 18 years old intending to start a self-composed cycle of AAS are included for participation. Study subjects will receive education and counseling aiming primarily to shorten the intended cycle duration, reduce the number of androgen types used, and use less other PIEDs. Through 1:1 randomization subjects are assigned to a one-time online consultation with a well-known fitness expert to receive information about diet and training regimens. Before (T0), during (T1) and after (T2) the cycle medical investigation take place (blood analysis, electrocardiography) and the results are discussed with the participants in an attempt to further limit their AAS use. At least 30 and at most 50 subjects of the entire cohort will also be analyzed for the occurrence of sleep apnea at those moments with the

use of the WatchPAT. About 1 year after inclusion a last follow-up moment (T3) takes place to document whether a subject started a new cycle after finishing the first.

Intervention

See 'study design'.

Study burden and risks

See paragraph E9.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Men of at least 18 years old.
• The subjects intents to start an androgen cycle within 2 weeks after enrollment.
• The planned cycle has an average weekly dose >250 mg and duration >6 weeks.

Exclusion criteria

• The use of AAS in the 3 months prior to enrollment (except for TRT <250 mg/week).
• When in the last 6 months:
1) A new somatic or psychiatric illness was diagnosed.
2) A medication for chronic illness was started or changed.
3) A (non-traumatic) hospital admission occured (or psychiatric ward admission).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2022
Enrollment:	100
Type:	Anticipated

Medical products/devices used

Generic name:	WatchPAT
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	02-06-2021
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	21-02-2022
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL77191.028.21