

What effect does testosterone gel have on female steroid levels?

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| Submission date 09/01/2019 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 11/01/2019 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 31/03/2025 | Condition category Nutritional, Metabolic, Endocrine | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Background and study aims

In the context of sport, steroids, principally testosterone, are the most used drugs for doping. However, since it is also a molecule produced by our own body, its detection is challenging and therefore requires new detection method development. In addition, the off-label use of clinical testosterone in women is increasing for the treatment of low libido. However, there is little information on the woman's metabolism response resulting from testosterone administration. This study should allow us to know to what extent the administration of transdermal testosterone influences the steroidal profile (blood and urine) of the healthy woman. Indeed, this route of administration is recognized to be the most frequently used for doping purposes.

Who can participate?

Healthy women, aged between 20 and 40 years, and not using hormonal contraception will be recruited for this study.

What does the study involve?

The study is an open-label trial, in which all participants will receive the same treatment. The study takes place over a period of 12 weeks divided into three main phases. Each phase corresponds to a menstrual cycle. The first phase is a follow-up phase during which no treatment is administered but with regular blood and urine collections to establish a baseline. It corresponds to the control phase. The second phase is that of intervention during which a testosterone gel (Tostran) will be applied daily (28 days) on the skin (abdomen and inner thighs) of the volunteers. The daily dose will be 0.5 g of gel corresponding to 10 mg of testosterone administered. Tostran is a testosterone gel approved and marketed in Switzerland. It is used in the substitution treatment of testosterone in adult men during various health problems caused by a deficiency of testosterone (male hypogonadism). The blood and urine samples are collected as in phase I. This phase is followed by phase III, called post-treatment, which is similar to phase I. No intervention is administered and only urine and blood samples are collected.

What are the possible benefits and risks of participating?

Participation in the study is a help for the fight against doping and for the improvement of female metabolism comprehension. The most frequently reported side effects linked to Tostran administration are local skin reactions due to the presence of butylhydroxytoluene (E321) in the

drug. It also happens that a long-term treatment causes swelling of the hands and / or feet, hair loss, hypertension, increased body hair, impaired biological balance, cutaneous hypersensitivity, acne , and oily skin.

Since the doses administered will be 6 times lower than those recommended for substitution treatment in humans, these adverse effects will be limited.

Where is the study run from?

This pilot study is conducted only in Switzerland, in Lausanne at the Centre Hospitalier Universitaire Vaudois (CHUV).

When is the study starting and how long is it expected to run for?

The study is supposed to start 01/03/2019 and will last approximately until 31/10/2019.

Who is funding the study?

The World Anti-Doping Agency (WADA).

Who is the main contact?

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Contact information

Type(s)

Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

2018-02106

Study information

Scientific Title

Establishment of the female steroid profile and impact of transdermal testosterone administration on the steroidal metabolism: open-label trial

Acronym

TestoFem

Study objectives

Transdermal testosterone administration influences the female steroid metabolism.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 04/06/2019, Canton de Vaud Human Research Ethics Commission (Av de Chailly 23, 1012 Lausanne, Switzerland; +41 213161830; Secretariat.CER@vd.ch), ref: 2018-02106

Study design

Single-centre open-label trial

Primary study design

Interventional

Secondary study design

Open-label trial

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

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

Health condition(s) or problem(s) studied

Steroid metabolism

Interventions

The trial is an open-label trial which means that every participant will receive the treatment and will know what is the treatment. A treatment with testosterone gel will be administered for 28 days. The product used for the study is Tostran 20 mg/g and 0.5 g of the product corresponding to 10 mg of testosterone will be applied daily on the skin of participants.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Tostran (testosterone gel)

Primary outcome measure

Serum testosterone concentration will be measured using UHPLC-MS/MS during the whole study.

Secondary outcome measures

1. Urinary and serum steroid profile with GC-MS and UHPLC-MS/MS before, during and after treatment.
2. Untargeted metabolomics study with UHPLC-HRMS for discovery of potential biomarkers of testosterone abuse with comparison of metabolic profile before, during and after treatment.
3. Analyses of urine samples with IRMS during the treatment phase.
4. Body composition measurement with DEXA scan before and after treatment.
5. Hematological profile with Sysmex XN-1000 during the whole study.
6. Endocrinological profile (LH, FSH, hCG, SHBG) during the whole study measured with clinical chemistry.
7. Self-esteem and quality of life using specific questionnaires (Rosenberg self-esteem scale and SF-96 questionnaire) before and after treatment.

Overall study start date

14/02/2018

Completion date

06/08/2020

Eligibility

Key inclusion criteria

1. Female
2. Aged 20-40 years old
3. Body mass index between 18 and 30 kg/m²
4. Hemoglobin concentration between 12 and 16 g/dL
5. Negative pregnancy test at screening
6. Basal testosterone concentration ≤ 1.5 nmol/L

7. Regular menstrual cycles (26-32 days)
8. Normal biological balance (complete blood count, liver function (ASAT / ALAT), CRP, renal function (creatinine))
9. Normal hormone balance (LH, FSH, SHBG, cortisol, prolactin)

Participant type(s)

Healthy volunteer

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

14

Total final enrolment

14

Key exclusion criteria

1. Hypertension (SBP> 140 and DBP> 90 mmHg)
2. Regular intake of tobacco (max 1 cigarette / day) or alcohol (max 1 drink / week)
3. Regular intake of anabolic or ergogenic drugs
4. Holder of a license in a sports discipline
5. Current acne or hirsutism deemed clinically significant
6. Dyslipidemia or hypercholesterolemia
7. Hyperprolactinaemia
8. Endocrine or metabolic disease
9. Tumor of pituitary gland or hypothalamus
10. Contraindications to the class of the substance administered (hypersensitivity or allergy to the active substance or to any of the excipients)
11. Treatment with synthetic anti-thyroid or thyroid hormones
12. Treatment with ketoconazole, anticoagulants, ACTH, corticosteroids
13. Cardiovascular, hepatic, renal or biliary disease
14. Current use of hormonal contraceptives or during the two months preceding the study
15. Pregnancy present or envisaged within 6 months after the end of the study
16. Breastfeeding
17. Eating disorders
18. Previous participation in another study in the last 30 days
19. Sports competition scheduled within 9 months after the end of the study
20. Donation of blood during the last 3 months
21. Migraine
22. Neoplasia or history of neoplasia

Date of first enrolment

01/03/2019

Date of final enrolment

31/03/2020

Locations

Countries of recruitment

Switzerland

Study participating centre

Centre de recherche clinique de la Faculté de biologie et médecine et du CHUV

Rue du Bugnon 44

Lausanne

Switzerland

1011

Study participating centre

Service d'endocrinologie, diabétologie et métabolisme du CHUV

Avenue de la Sallaz 8

Lausanne

Switzerland

1011

Sponsor information

Organisation

Research and Expertise in antiDoping sciences - Université de Lausanne

Sponsor details

Research and Expertise in antiDoping sciences-REDS

ISSUL-Institut des Sciences du sport

Synathlon-Quartier Centre

Lausanne

Switzerland

1015

Sponsor type

University/education

Website

<https://www.unil.ch/reds/fr/home.html>

ROR

<https://ror.org/019whta54>

Funder(s)

Funder type

Other

Funder Name

World Anti-Doping Agency

Alternative Name(s)

l'Agence mondiale antidopage, WADA, AMA

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

Canada

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

31/05/2021

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| Results article | | | 11/05/2021 | Yes | No |
| Results article | | 29/03/2025 | 31/03/2025 | Yes | No |