

# Monitoring testosterone replacement therapy - a strategy for distinguishing real and falsely high concentrations of testosterone.

Published: 12-12-2022

Last updated: 21-09-2024

The goal of this study is to asses wheter testosterone contamination is caused by appliction of testosterone gel on the phlebotomy site or on the forearm.If previously mentioned study is supported by the current study, the testosterone/estradiol...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Other condition
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON51953

### Source

ToetsingOnline

### Brief title

Study on the detection of falsely high testosterone concentrations

### Condition

- Other condition

### Synonym

genderdysphoria, genderincongruence

### Health condition

genderdysforie

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Vrije Universiteit Medisch Centrum

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** androgel, hormone therapy, laboratory measurement, testosterone

## Outcome measures

### Primary outcome

testosterone and estradiol concentration in the blood

### Secondary outcome

none

## Study description

### Background summary

During the monitoring of the hormone status of transmen, higher testosterone levels than expected are regularly found.

One possible explanation is that it is caused by phlebotomy from the elbow on which on the testosterone gel is applicated. In the body, testosterone is converted to estradiol, which results in a correlated rise in estradiol in case of a high testosteron. However, this is not the case for testosterone from the phlebotomy site, which theoretically results in a higher testosterone/estradiol ratio.

Another possible explanation for higher than expected testosterone concentrations is that the gel was applied on the forearm, distal to the venipuncture site, causing a high testosterone concentration in the venous bloodstream of that arm.

If this is the case, this is of great importance for patients and health care providers in clinical practice.

By analysing existing data, testosterone gel users turned out to have a higher testosterone/estradiol ratio than testosteron injection users.

This assumes we're on the right track.

## Study objective

The goal of this study is to assess whether testosterone contamination is caused by application of testosterone gel on the phlebotomy site or on the forearm. If previously mentioned study is supported by the current study, the testosterone/estradiol value can be used in clinical practice to detect falsely high testosterone levels and hence upgrade the quality of care.

## Study design

We would like to take blood of 7 transmen, from the gel applied arm and from the other arm

## Study burden and risks

One extra venapuncture at a moment when blood is already taken

## Contacts

### Public

Vrije Universiteit Medisch Centrum

De Boelelaan 1117  
Amsterdam 1081HV  
NL

### Scientific

Vrije Universiteit Medisch Centrum

De Boelelaan 1117  
Amsterdam 1081HV  
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

## Age

Adults (18-64 years)

## Inclusion criteria

Status after gonadectomy, use of testosterone gel 40.5/50mg-100, usual time of administration of testosterone gel in the morning, appointment time at the outpatient clinic between 8:30 and 12:00, need for the measurement of the testosterone concentration in the blood in the context of patient care

## Exclusion criteria

Use of estrogens

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 04-05-2023

Enrollment: 7

Type: Actual

## Ethics review

Approved WMO

Date: 12-12-2022

Application type: First submission

Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	11-09-2024
Application type:	Amendment
Review commission:	METC Amsterdam UMC

## 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	NL77574.029.21