plasma testosterone levels in hypogonadal individuals treated with AndroGel, impact of showering shortly after application

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to investigate whether showering shortly after Androgel application adversly affects plasma testosterone levels.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Endocrine disorders of gonadal function
Study type	Interventional

Summary

ID

NL-OMON32664

Source
ToetsingOnline

Brief title
androgel shower study

Condition

- Endocrine disorders of gonadal function

Synonym
hypogonadism

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Goodlife Healthcare bv

Intervention

Keyword: gel, testosterone, transfer

Outcome measures

Primary outcome

maximal testosterone level

area under the curve

time average concentration

Secondary outcome

na

Study description

Background summary

Androgel (transdermal testosterone) is the most used mode of androgen supplementation in the Netherlands. A potential drwaback associated with the use of this gel is the potential of unvoluntary testosterone transfer to women and children. Taking a shower after application of the gel prevents significant transfer, however it may potentially diminish testosteron uptake by the skin.

Study objective

to investigate whether showering shortly after Androgel application adversly affects plasma testosterone levels.

Study design

prospective, randomized, cross-over

Intervention

during three weeks Androgel 50 mg in three regimes of one week
-application after showering
-application 15 minutes before showering
-application 30 minutes before showering

Study burden and risks

the use of Androgel 50 mg (very low risk, low burden)
on three days, at the end of every study week at 5 time points blood is drawn (7 ml; 15 blood tests in total) at 08:00 h, 09:00 h, 12:00 h, 16:00h, 18:00h (low risk, moderate burden)

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

female-to male transsexual after gonadectomy
age 18-60 years

Exclusion criteria

known intolerance for a Androgel
chronic skin condition

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2009
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	12-11-2008
Application type:	First submission
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	NL24711.029.08