Conjugated androgen metabolites: a novel biomarker for androgen exposure in hirsutism?

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON56909

Source
ToetsingOnline

Brief title
HAIR

Condition

- Other condition

Synonym
Excessive hair growth in women, hirsutism

Health condition

Endocriene aandoeningen van de bijnier/gonadale functie/perifere weefsels

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: uit reserves van de afdeling.

Intervention

Keyword: Conjugated androgen metabolites, Hirsutism, Laboratory measurements

Outcome measures

Primary outcome

- Conjugated androgen metabolites: 3α-diol-3G, 3α-diol-17G, ADT-G

- 3G/17G-ratio

Secondary outcome

- Results of the psychological questionnaire

- HOMA-index (serum measurement)

- HbA1c, fasting insulin and glucose

- Lipid profile (serum total cholesterol, LDL, VLDL, HDL, triglycerides)

- Liver enzymes (serum ALP, ALT, AST, GGT, ELF)

Study description

Background summary

Hirsutism, the excessive growth of terminal hair in a man-like pattern in a female, is the most important clinical sign of androgen excess in women. However, not all patients with hirsutism have elevated serum levels of testosterone (T) or androstenedione (A4), which is called idiopathic hirsutism (IH). This is explained by the fact that the majority of androgens in women are produced in the same peripheral tissue cells as where they exert their action in (e.g. the skin), with only a minimal release of T and A4 into the general circulation. However, conjugated androgen metabolites do diffuse into the general circulation where they can be measured before elimination by the kidneys. Conjugated androgen metabolites, such as 3α-androstanediol glucuronide (3α-diol-G) and androsterone glucuronide (ADT-G), have previously been

discussed to reflect peripheral androgen exposure, and could therefore serve as a better biomarker for androgen exposure in IH.
Our hypothesis is that conjugated androgen metabolites could serve as a biomarker for increased androgen exposure in women with hirsutism, irrespective of serum T and A4 levels. If so, patients with IH might also benefit from anti-androgenic medication.

Study objective

The aim of this study is to investigate whether conjugated androgen metabolites (i.e. 3α-diol-G and ADT-G) could serve as a biomarker for increased androgen exposure in women with hirsutism, irrespective of serum T and A4 levels. The second aim of this study is to investigate whether hirsutism is associated with a decreased metabolic, cardiovascular and psychological health.

Study design

A case control study.

Study burden and risks

First, participants will be asked to complete a short survey containing questions about one*s presence of excessive hair growth, menstrual pattern, evident endocrine diagnoses and medicine use. This survey is the first step of our screening and selection procedure and will be used to characterize the participants and to establish the likelihood of having polycystic ovary syndrome (PCOS). Based on the survey, we will invite 20 women with hirsutism and PCOS and 20 women with hirsutism without PCOS. In addition, we will recruit 40 control women from the general population.
In all these 80 subjects we will assess hair growth on four different locations on the skin (i.e. upper lip, chin, lower abdomen and thighs) with a validated digital microscope camera. Furthermore, four tubes of blood (22 mL in total) will be drawn through venous blood sampling. The measurement of endocrine laboratory parameters is the second step in our selection procedure and aims to characterize our patients biochemically. Finally, participants will be asked to complete one questionnaire concerning their psychological wellbeing (degree of depression, anxiety and overall quality of life) and more specific questions concerning the psychological impact of (excessive) hair growth. The risks of participation are considered negligible.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Premenopausal women (18-40 years) with hirsutism:
- Ability to provide informed consent;
- Ability to speak and understand Dutch;
- The presence of hirsutism.

Healthy premenopausal women (18-40 years):
- Ability to provide informed consent;
- Ability to speak and understand Dutch;
- Consider themselves healthy; no signs of hirsutism, hyperandrogenism or other endocrine pathologies.

Exclusion criteria

Premenopausal women (18-40 years) with and without hirsutism:
- Primary ovarian insufficiency (POI) or premature ovarian failure (POF);
- Pregnancy;
- Any of the following medications:
o Oral contraceptives

o Anocrine/danazol;
o Minoxidil;
o Fluoxetine;
o Celestone;
o Dexamethasone;
o Hydrocortisone;
o (Methyl)prednisolone;
o Prednisone;
o Spironolactone;
o Flutamide;
o Finasteride;
o Cimetidine;
o Anabolic steroids.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-11-2024
Enrollment:	80
Type:	Actual

Medical products/devices used

Generic name:	Handheld digital microscope camera
Registration:	No

Ethics review

Approved WMO Date:	12-06-2024
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	NL85783.018.24