

## UCLA study to examine hyperandrogenism and Polycystic Ovarian Syndrome (PCOS)



**UCLA physicians are conducting a study** of the effects of excess androgen in women with Polycystic Ovarian Syndrome (PCOS). UCLA is seeking both women who have been diagnosed with PCOS and women without PCOS to take part in the study, for which they will be compensated.

PCOS is one of the most common endocrine disorders among women of reproductive age, affecting up to 10 percent of reproductive-age women. “Polycystic” refers to the accumulation of multiple small follicles in the ovaries that do not fully develop. PCOS can cause menstrual irregularities, excess hair growth and acne, and tends to produce worse symptoms in obese women. The condition can also impair glucose tolerance, potentially leading to type 2 diabetes, and is associated with cholesterol and lipid abnormalities that can potentially increase the risk for cardiovascular disease.

### Androgen excess in PCOS

Most women with PCOS exhibit hyperandrogenism, or androgen excess. A current theory is that an excess of androgen can interfere with the normal accumulation of lipids in subcutaneous fat cells, leading to the harmful deposit of fat in other body tissues.

### Understanding the mechanism of this disorder will guide future treatment

“Up until now, the sugar metabolism, fat deposition and ovarian function aspects of PCOS have been seen as a constellation of symptoms, but there’s been no evidence that ties them to a single cause,” says Daniel Dumesic, MD, principal investigator and Division Chief of Reproductive Endocrinology and Infertility. “Our intent is to determine if androgen excess in PCOS women provides a logical way to explain not only their ovarian dysfunction, but also lipid and cholesterol issues and sugar metabolism irregularities.”

If the effects of androgen excess are borne out by research results, a single therapeutic agent may be able to restore much of patients’ normal function in these areas.

Dr. Dumesic also hopes that the highly accurate data collected during the study will establish more rigorous standards for PCOS diagnosis. He says, “If we are stringent in our diagnosis and understand the mechanisms of the disease, we can provide appropriate treatment for PCOS women and properly distinguish them from others who store fat normally and therefore have different medical needs.”

When excess lipids are stored in the liver, for example, it can upset normal lipid levels in the circulation and potentially lead to cardiovascular problems. Excess lipids deposited in skeletal muscle tissue can impair insulin action and promote insulin resistance, leading to an increased risk of developing type 2 diabetes mellitus. Excess lipids and cholesterol stored in the ovaries may also lead to abnormal hormone production, causing menstrual irregularities. Anti-androgen therapy may counter these adverse effects of androgen excess in the body by improving normal subcutaneous fat storage.

## Clinical study recruitment

An NIH-funded clinical study entitled *Androgen Excess as a Mechanism for Adipogenic Dysfunction in Polycystic Ovarian Syndrome (PCOS) Women*, is under way at UCLA. Researchers will be collecting data on study participants' sugar metabolism, fat deposition and ovarian function — all of which are affected by PCOS — to determine if controlling androgen excess leads to more normal function.

Because obesity can confound these data for PCOS women, and because different racial backgrounds are associated with differences in body fat at a given weight, researchers are recruiting Non-Hispanic Caucasian women between the ages of 18 and 35 years with a BMI (body mass index) between 18.5 and 25 kg/m<sup>2</sup>. As the anti-androgen drug used in the study would be harmful to a male fetus, study participants cannot be pregnant or planning to become pregnant. Participants cannot have a pacemaker, metal implants, or be claustrophobic.

## Clinical trial plan

Women participating in the study will undergo medical tests to determine their insulin sensitivity, fat storage and response to ovarian hormones. Tests will include:

- Frequently sampled glucose tolerance testing
- DXA scanning (for total body fat)
- MRI (to determine the percentage of subcutaneous fat versus intra-abdominal fat)
- Vaginal ultrasound (for ovarian size)
- FSH (follicle-stimulating hormone — for ovarian hormonal response)
- Removal of a small amount of subcutaneous fat from the lower-abdominal region (to determine fat cell function)

Women without PCOS complete participation after the initial round of medical tests. Women with PCOS will take either Flutamide or placebo pills every day for six months. Flutamide temporarily blocks the action of male hormone. After six months on either the study drug or placebo, the tests are repeated.

Researchers will share all individual test results with the study participants, which can be helpful to both the normal and PCOS women in managing their risk of diabetes and cardiovascular disease, as well as their reproductive health. Women without PCOS can receive up to \$300 for participating in the study; those with PCOS can receive up to \$840.

## Participating Physicians

### Daniel Dumesic, MD

Principal Investigator, Androgen Excess as a Mechanism for Adipogenic Dysfunction in Polycystic Ovarian Syndrome (PCOS) Women  
Division Chief and Professor  
Reproductive Endocrinology and Infertility

## Contact Information

To learn more about the study, call (310) 825-0580 or e-mail [uclaobgynresearch@mednet.ucla.edu](mailto:uclaobgynresearch@mednet.ucla.edu). In order to protect your privacy, please do not include any personal health information in your message.

A member of the study team will contact you to discuss the study and to determine if you are eligible to participate.