



# Treating PCOS with a combination of oral contraceptives and spironolactone does not increase the risk of diabetes or heart disease

In women with polycystic ovary syndrome (PCOS), the most effective treatment is a combination of the oral contraceptive pill (OCP) with an anti-androgen, which does not increase the risk of metabolic or cardiovascular complications, according to a study published in the <u>European Journal of Endocrinology</u>. The findings should lead to more women being prescribed the most effective treatment for their condition.

PCOS is a common condition, affecting approximately 20% of women globally, in which elevated male hormone levels (androgens) can cause a range of distressing and life-limiting symptoms, including reduced fertility, irregular periods, excessive facial and body hair, and acne. There is currently no cure for PCOS, so present treatments aim to manage the symptoms. This has included OCPs, which were an effective treatment for many of the associated symptoms, amongst women not planning to become pregnant. However, during the past two decades, concerns over the increased incidence of insulin resistance and elevated cardiovascular risk factors exhibited by PCOS patients have been partly attributed to the contraceptive-based therapy and resulted in doctors limiting the use of OCPs for PCOS treatment, in favour of insulin sensitiser drugs, such as metformin.

The present study, by researchers at Hospital Universitario Ramón y Cajal and the University of Alcala found no evidence for increased risk of these cardiometabolic complications with the combined treatment of OCP plus the anti-androgen, spironolactone. This suggests that some PCOS patients may have been prescribed alternative, less effective treatments on unwarranted safety fears.

In the study, 46 women with severe PCOS were split into two groups; one group was prescribed the insulin sensitiser, metformin, whilst the other was treated with oral contraceptives plus spironolactone. Over the course of one year the women were assessed on a number of measures that gauged the severity of their PCOS symptoms, metabolic health and cardiovascular risk factors. The researchers found that OCP plus spironolactone was not only more effective in treating PCOS symptoms but was not associated with any increased risk of metabolic or cardiovascular complications. These findings suggest that fears about the safety of OCPs may be unfounded and that combination therapy with an anti-androgen remains the optimal treatment for PCOS. Furthermore, these data suggest that the androgen excess associated with PCOS may contribute to metabolic dysfunction and increased cardiovascular risk factors exhibited by patients, therefore OCP plus and anti-androgen, is more effective at addressing more PCOS symptoms.





Professor Héctor F. Escobar-Morreale said, "According to our present results oral contraceptives plus spironolactone is a much more effective treatment than metformin, showing excellent tolerability and safety, with no increased risk of metabolic dysfunction or cardiovascular risk factors."

Whilst the combined treatment proved more effective and safe over the course of one year, the longer term effects of OCPs need to be addressed. Ideally, these would be assessed and the present findings could be confirmed and extended in larger, randomised clinical trials. Prof Escobar-Morreale and colleagues are now conducting a meta-analysis of all published data on the use of OCPs, anti-androgens or insulin sensitisers for PCOS treatment, in order to support an evidence-based update to current guidelines on the treatment of PCOS and to ensure patients are receiving the most effective and safest therapy.

Professor Escobar-Morreale stated, "An evidence-based update to the PCOS treatment guidelines could lead to enhanced quality of life and improved long-term outcomes for patients."



### **Notes for Editors**

1. For further information about the study please contact:

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- The study, "Combined oral contraceptives plus spironolactone compared with metformin in women with polycystic ovary syndrome: a one year randomized clinical trial", was published in the European Journal of Endocrinology on the 15 September 2017. For copies of the study please contact the press office at media@bioscientifica.com.
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- 4. <u>European Journal of Endocrinology</u> (EJE) is the official clinical journal of the European Society of Endocrinology, publishing high-quality original research and review articles on all aspects of clinical and translational endocrinology from around the globe. <u>European Journal of Endocrinology</u> is published by <u>Bioscientifica</u>.
- 5. At the <u>European Society of Endocrinology</u> (ESE), we are working together to develop and share the best knowledge in endocrine science and medicine. ESE represents a community of over 20,000 European endocrinologists, enabling us to inform policy makers on health decisions at the highest level through engagement in advocacy efforts across Europe. It is by uniting and representing every part of the endocrine community that we are placed in the best possible position to improve life for the patient.