

PROJECT

# SPIOMET4HEALTH

## Polycystic Ovary Syndrome (PCOS) In Adolescent Girls And Young Women: Toward A Treatment Guided By Pathophysiology

The main objective of SPIOMET4HEALTH is to test, in a multi-centre Phase II clinical trial, a novel treatment for adolescent girls and young adult women with PCOS.

**zabala**  
INNOVATION



This project has received funding from the European Union's Horizon 2020 Research And Innovation Programme under grant agreement N° 899671

**17**

PARTNERS

**9**

COUNTRIES

**€6 M**

TOTAL BUDGET

**5**

YEARS

**spiomet**  
**4 health**

### IN ONE CLICK

| Coordinator               | Programme         | Period    |
|---------------------------|-------------------|-----------|
| Fundació Sant Joan de Déu | Horizon2020       | 2021-2026 |
| Sector                    | Web               |           |
| Health                    | spiomet4health.eu |           |

### 01 Challenge

Polycystic Ovary Syndrome (PCOS) is the most prevalent chronic endocrine-metabolic disorder in women of reproductive age, affecting 5-10% of women worldwide. It is the most frequent cause of anovulatory subfertility, and it is also associated with lifelong co-morbidities such as type 2 diabetes, premature vascular aging, premenopausal cancer and anxiety/depression. There is currently no approved treatment for PCOS in adolescent and young women, approximately 98% of whom are prescribed oral contraceptives (OCs) off-label. OCs do alleviate key symptoms, such as hirsutism and menstrual irregularity, but do not revert the underlying pathophysiology, and patients remain at risk for post-treatment subfertility.

### 02 Solution

Previous studies by FSJD and Katholieke Universiteit Leuven have led to the identification of a treatment (SPIOMET) consisting of two "insulin sensitisers" (pioglitazone [PIO] and metformin [MET]) and a mixed anti-androgen and anti-mineralocorticoid (spironolactone [SPI], which also acts as a brown adipose tissue activator. However, these studies had some limitations that SPIOMET4HEALTH aims to overcome. The project will test a novel treatment consisting of SPIOMET in a single tablet (SPI, 50 mg; PIO, 7.5 mg and MET, 850 mg) administered daily, in combination with lifestyle measures. It aims at normalizing ovulation and endocrine-metabolic status through reduction of hepato-visceral fat excess.

### 03 Impacts

SPIOMET4Health could change the current paradigm of PCOS treatment, as the new therapy will not only target the gonadotropic axis, but also the underlying pathophysiology. This strategy should also reduce the psychosocial impact and economic burden of PCOS on healthcare systems. SPIOMET4HEALTH can also become a preconception strategy to be followed by spontaneous ovulation/conception, normal pregnancy and a healthier next generation.