

1. General Information

Cohort ID	5007_20
Title (Study Name)	ProPCO-RCT Probiotic dietary Intervention in Polycystic Ovary Syndrome – A Randomized Controlled Trial
Principal investigator	Prof. ⁱⁿ Barbara Obermayer- Pietsch
Contact information	pm-biobank@medunigraz.at
Funding agency	Sponsor: Medical University of Graz

2. Description

<p>Polycystic Ovary Syndrome (PCOS) is a condition characterized by increased male sex hormones, irregular menstrual cycles, infertility, obesity, diabetes and other symptoms and complications. It is usually treated with lifestyle changes, hormonal contraceptives ("the pill") or with metformin, an antidiabetic drug.</p> <p>We want to assess the possibility of treating PCOS with probiotics, as gut bacteria are known to affect hormonal and metabolic functions. For that purpose, we designed this 6-month intervention trial, in which 60 women per group ingest either a probiotic, a placebo or metformin. In the end hormones, sugar metabolism and other PCOS criteria are evaluated.</p>

3. Details

ICD 10/O codes / Healthy	E28.2	
Key words	PCOS, probiotics, metformin, RCT, testosterone	
Collection / Cohort size 12/2022	1.810 aliquots from 99 patients	
Informed Consent (IC)	<input checked="" type="checkbox"/> Broad Biobank IC	
	<input checked="" type="checkbox"/> Specific Study IC	
Status	<input checked="" type="checkbox"/> In progress / compl. date: 12/2023	
	<input type="checkbox"/> Completed	
Inclusion criteria	Age distribution	18+
	Sex distribution (f:m)	100% female
	Others	<p>Women with PCOS - two out of three criteria have to be met:</p> <ul style="list-style-type: none"> • clinical or biochemical hyperandrogenism • irregular menstrual cycles • polycystic ovarian morphology
Earliest access	As of now	
Quality-standards	<input checked="" type="checkbox"/> ISO 9001:2015 (SOPs)	
Associated publications / references	<p>Mulhall JP, Trost LW, Brannigan RE, Kurtz EG, Redmon JB, Chiles KA, et al. Evaluation and Management of Testosterone Deficiency: AUA Guideline. J Urol [Internet]. 2018 [cited 2019 Oct 22];200(2):423–32. Available from: http://www.ncbi.nlm.nih.gov/pubmed/29601923</p>	

	<p>Gaberšček S, Zaletel K, Schwetz V, Pieber T, Obermayer-Pietsch B, Lerchbaum E. MECHANISMS IN ENDOCRINOLOGY: Thyroid and polycystic ovary syndrome. Eur J Endocrinol. 2014;172(1):R9–21. Available from: https://pubmed.ncbi.nlm.nih.gov/25422352/</p> <p>Lindheim L, Bashir M, Münzker J, Trummer C, Zachhuber V, Leber B, et al. Alterations in gut microbiome composition and barrier function are associated with reproductive and metabolic defects in women with polycystic ovary syndrome (PCOS): A pilot study. PLoS One. 2017;12(1):1–20. Available from: https://pubmed.ncbi.nlm.nih.gov/28045919/</p> <p>Haudum C, Lindheim L, Ascani A, Trummer C, Horvath A, Münzker J, et al. Impact of short-term isoflavone intervention in polycystic ovary syndrome (PCOS) patients on microbiota composition and metagenomics. Nutrients [Internet]. 2020 Jun 1 [cited 2020 Aug 25];12(6). Available from: https://pubmed.ncbi.nlm.nih.gov/32492805/</p>
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4. Material available (aliquot size) and storage conditions

Material	<input checked="" type="checkbox"/> Serum (580 µl)	<input checked="" type="checkbox"/> -80°C
	<input checked="" type="checkbox"/> EDTA plasma (580 µl)	<input checked="" type="checkbox"/> -80°C
	<input checked="" type="checkbox"/> EDTA Buffy coat (300 µl)	<input checked="" type="checkbox"/> -80°C
	<input checked="" type="checkbox"/> Spontaneous urine (580 µl)	<input checked="" type="checkbox"/> -80°C

Dokument erstellt (tt/mm/yyyy): 21/04/2021	Letzte inhaltliche Aktualisierung (tt/mm/yyyy): 04/08/2023
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