

## 1. General Information

<b>Cohort ID</b>	5007_20
<b>Title (Study Name)</b>	ProPCO-RCT Probiotic dietary Intervention in Polycystic Ovary Syndrome – A Randomized Controlled Trial
<b>Principal investigator</b>	Prof. <sup>in</sup> Barbara Obermayer- Pietsch
<b>Contact information</b>	<a href="mailto:pm-biobank@medunigraz.at">pm-biobank@medunigraz.at</a>
<b>Funding agency</b>	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>
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## 3. Details

<b>ICD 10/O codes / Healthy</b>	E28.2	
<b>Key words</b>	PCOS, probiotics, metformin, RCT, testosterone	
<b>Collection / Cohort size</b> 12/2023	2.430 aliquots from 111 patients	
<b>Informed Consent (IC)</b>	<input checked="" type="checkbox"/> Broad Biobank IC	
	<input checked="" type="checkbox"/> Specific Study IC	
<b>Status</b>	<input checked="" type="checkbox"/> In progress / compl. date: 12/2023	
	<input type="checkbox"/> Completed	
<b>Inclusion criteria</b>	<b>Age distribution</b>	18+
	<b>Sex distribution (f:m)</b>	100% female
	<b>Others</b>	<p>Women with PCOS - two out of three criteria have to be met:</p> <ul style="list-style-type: none"> <li>clinical or biochemical hyperandrogenism</li> <li>irregular menstrual cycles</li> <li>polycystic ovarian morphology</li> </ul>
<b>Earliest access</b>	As of now	
<b>Quality-standards</b>	<input checked="" type="checkbox"/> ISO 9001:2015 (SOPs)	
<b>Associated publications / references</b>	<p><u>Evaluation and Management of Testosterone Deficiency: AUA Guideline.</u>          Mulhall JP, Trost LW, Brannigan RE, Kurtz EG, Redmon JB, Chiles KA, et al.  <a href="http://www.ncbi.nlm.nih.gov/pubmed/29601923">http://www.ncbi.nlm.nih.gov/pubmed/29601923</a></p>	

	<p><u>MECHANISMS IN ENDOCRINOLOGY: Thyroid and polycystic ovary syndrome.</u> Gaberšček S, Zaletel K, Schwetz V, Pieber T, Obermayer-Pietsch B, Lerchbaum E. <a href="https://pubmed.ncbi.nlm.nih.gov/25422352/">https://pubmed.ncbi.nlm.nih.gov/25422352/</a></p> <p><u>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.</u> Lindheim L, Bashir M, Münzker J, Trummer C, Zachhuber V, Leber B, et al. <a href="https://pubmed.ncbi.nlm.nih.gov/28045919/">https://pubmed.ncbi.nlm.nih.gov/28045919/</a></p> <p><u>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.</u> Nutrients [Internet]. 2020 Jun 1 [cited 2020 Aug 25];12(6). Available from: <a href="https://pubmed.ncbi.nlm.nih.gov/32492805/">https://pubmed.ncbi.nlm.nih.gov/32492805/</a></p> <p><u>Identification of Novel Intronic SNPs in Transporter Genes Associated with Metformin Side Effects.</u> Schweighofer N, Strasser M, Obermayer A, Trummer O, Sourij H, Sourij C, Obermayer-Pietsch B. <a href="https://pubmed.ncbi.nlm.nih.gov/37628660/">https://pubmed.ncbi.nlm.nih.gov/37628660/</a></p>
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#### 4. Material available (aliquot size) and storage conditions

<b>Material</b>	<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

<b>Dokument erstellt</b> (tt/mm/yyyy): 21/04/2021	<b>Letzte inhaltliche Aktualisierung</b> (tt/mm/yyyy): 19/03/2024
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