

VUMC Progesterone Study Info and Links

Info

- **Scientific title:** Progesterone for Breast Development in Trans Women; Assessment of effects and safety: a pilot trial
- **Lay title:** Does progesterone treatment of trans women lead to increased breast development and are there side effects? A pilot trial.
- **Sponsor/institution:** Amsterdam UMC, location VUmc, Netherlands
- **Investigators:** Martin den Heijer, Benthe Dijkman, Christel de Blok, Koen Dreijerink
- **Identifiers:** NL73840.029.20; NL9086; EUCTR2020-001952-16-NL; 2020-001952-16
- **Contact:** progesteronstudie@amsterdamumc.nl

- **Trial overview:**

"n=90 RCT with 6 arms -> 4 arms with E2 + P4 at different doses and 2 arms with E2 without P4; in one of the arms, E2 dose is "increased" (progressively?)

 - 12 months initial study period with follow ups at 0, 3, 6, and 12 months
 - 3D breast volume measurements
 - Also monitoring mood, sleep, side effects, labs, etc.
 - VUMC stopped using CPA recently so it's GnRHa as AA now (?)
 - VUMC is using LC-MS so P4 labs should hopefully be accurate
 - Will likely have follow-up studies testing other P4 routes, like rectal and transdermal"

Links

Social Media Discussion and Study Info Sheet PDF

- <https://discord.com/channels/438306949285806082/438308040446574592/82222612562640900> (study info sheet PDF)
 - https://files.transfemscience.org/pdfs/misc/VUMC%20Progesterone%20Study%20Dutch%20Original%20%5BProefpersoneninformatiebrief_Progesteronstudie%5D.pdf
 - <https://files.transfemscience.org/pdfs/misc/VUMC%20Progesterone%20Study%20English%20Translated%20%5BProgesterone%20Study%20Test%20Subject%20Information%20Letter%5D.pdf>
- <https://discord.com/channels/438306949285806082/442512154680098834/803755280847994901>
- <https://discord.com/channels/438306949285806082/442512154680098834/795355517945249792>
- https://www.reddit.com/r/AskMtFHRT/comments/m16oq1/first_trans_progesterone_study/

Clinical Trial Registries

- https://www.clinicaltrialsregister.eu/ctr-search/search?query=eudract_number:2020-001952-16
- <https://www.clinicaltrialsregister.eu/ctr-search/trial/2020-001952-16/NL>
- <https://trialsearch.who.int/Trial2.aspx?TrialID=EUCTR2020-001952-16-NL>

- <https://www.trialregister.nl/trial/9086> (broken)
- <https://web.archive.org/web/20220116124939/https://www.trialregister.nl/trial/9086> (broken)

Miscellaneous

- <https://www.amsterdamumc.org/en/research/institutes/amsterdam-gastroenterology-endocrinology-metabolism/news/agem-clinical-grants-2020-awarded.htm#:~:text=Progesterone%20for%20Breast%20Development%20in%20Trans%20Women%3B%20Assessment%20of%20effects%20and%20safety>