Identifizierung von Targetgenen und Biomarkern bei Patientinnen mit Endometriose - EMMA	Prof. Dr. René Wenzl, MSc	Prof. Dr. Harald Zeisler Dr. Christine Staudigl Dr. Lorenz Küssel Dr. Petra Pateisky	Amtsforschung	laufend	150	MedUni Wien
A randomized, double blind, placebo-controlled study to evaluate the Safety and Efficacy of Elagolix in Subjects with Moderate to severe Endometriosis-associated pain	Prof. Dr. René Wenzl, MSc	Dr. Petra Pateisky	§ 27	01.12.2013- 31.12.2015	0	AbbVie GmbH
Circulating miRNAs as new endometriosis-related biomarker candidates	Prof. Dr. René Wenzl, MSc	Dr. Petra Pateisky Dr. Iveta Yotova	§ 27	01.07.2013- 31.12.2015	80	Bayer HealthCare Pharmaceutical

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Identifizierung von Targetgenen und Biomarkern bei Patientinnen mit Endometriose - EMMA

Studienziel:
Das Ziel der Studie ist es, in Patientinnenmaterial Zielmoleküle, insbesondere Proteine, die von Genen kodiert werden, oder ihren Vorstufen, die so genannte MRNA, die differenziell in Käsionen sowie im Patientinnenblut expremiert sind, zu finden. Ein weiteres Ziel dieser Studie ist es, in Patientinnenmaterial Biomarker, die die Diagnose Endometriose und/oder eine Verlaufskontrolle einer Therapie ermöglichen zu finden

Einschlusskriterien:
- Prämenopausale Frauen im Alter 18-50 Jahre
- Einverständniserklärung liegt vor

Ausschlusskriterien:
- Maligne Erkrankungen
  - Aktuelle maligne Erkrankungen
  - < 10 Jahre nach Mamma.CA
  - < 5 Jahre nach sonstigen Tumoren
  - Eine prämaligne Läsion der Cervix ist kein Ausschlusskriterium
- Entzündungen und Infektionen
  - HIV-Infektion, Hepatitis A, B, C; Tuberkulose
  - Systemische Autoimmunerkrankungen (system. Lupus erythematodes, rheumathoide Arthritis o.ä.)

Ansprechpartner:
Univ. Prof. Dr. René Wenzl, MSc

Sponsoren:
Bayer Pharma AG

Kontaktperson:
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A Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety and Efficacy of Elagolix in Subjects with Moderate to Severe Endometriosis-Associated Pain Incorporating Amendment

Studienziel:

The primary objective of this study is to evaluate the safety, tolerability and efficacy of elagolix, administered once daily or twice daily for 3 months in the management of moderate to severe endometriosis-associated pain and to evaluate the effect of elagolix treatment on analgesic use for endometriosis-associated pain. Secondary efficacy objectives include evaluation of persistence of efficacy at 6 months and assessments of other endometriosis-related symtoms, analgesic use, as well as QoL endpoints.

The co-primary efficacy endpoints will be the proportion of responders at Month 3 based upon the mutually-exclusive scales for daily assessment of DYS and NMPP measured by the modified Biberoglu and Behrman scales using the electronic daily dairy. Use of analgesic medication for endometriosis-associated pain will be included in the responder definition. These endpoints will also be assessed at 6 months for assessment of persistence of efficacy. The secondary efficacy objectives will be assessed using e-Diary data and QoL questionnaires.

The safety and tolerability objectives include the assessment of BMD via DXA and endometrial health via transvaginal ultasound at 6 months. In addition, subjects will be counseled at every visit on the importance of pregnancy prevention and use of appropriate and effective methods of birth control during each study period. Standard safety parameters, in addition to hypoestrogenic adverse events of interest, will be also be assessed.

Einschlusskriterien:

- Premenopausal female age 18 and 49 years, inclusive
- Documented surgical diagnosis of endometriosis (laparoscopy or laparotomy) performed within 7 years of entry into Washout or Screening
  - Surgical or Pathology report
  - Physician note
- Agree to switch from current analgesic rescue medication to only those permited by the protocol from Screening through Post-treatment Month 6
- Agrees to use 2 forms of non-hormonal contraception during the Washout, Screening, Treatment and Post-treatment Follow-Up Period through Month 6
- While in Washout
  - Had two normal menstrual cycles (28 days ± 5 days) immediately prior to entering the Screening period.
- While in Screening
  - Had at least two regular menstrual cycles (28 days ± 5 days) within the screening period prior to Day 1
  - Had at least 45 days of e-Diary entries

Ausschlusskriterien:

- Subject is:
  - Pregnant, breast feeding, or planning a pregnancy n next 24 Months
  - < 6 Months postpartum, post-abortion, at Screening
- Subject has:
  - Intra-uterine device (IUD); subject is eligible if removed ans WO complete
  - Previous non-response to GnRH agonists/antagonists, DMPA, or aromatase inhibitors – partial response or side effects not exclusionary
  - Condition(s) that require chronic therapy that may interfere with the assessment of endo-related pain

- Chronic pelvic pain not caused by endometriosis (e.g.; interstitial cystitis)
- Chronic pain syndrome (e.g., fibromyalgia)

- Undiagnosed abnormal genital bleeding
- Clinically significant gynecologic condition on TVU/endometrial biopsy

- Subject has history of:
  - Osteoporosis or other metabolic bonde disease
  - Major depression or post-traumatic stress disorder (PTSD) w/i 2 years of screening, OR a history of other major psychiatric disorder at any time (e.g., schizophrenia, bipolar disorder)
  - >2 weeks of continuous use of a prohibited long-acting narcotic or immediate release narcotic for treatment of endo pain within 6 Months
  - Previous participation in an elagolix study or participation in any investigational study within 2 months prior to Screening

Ansprechpartner:
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