

**PLEASE NOTE:** *This trial has been registered retrospectively.*

## Trial Description

### Title

**Partnership, experience of pain and psychological stress in endometriosis**

### Trial Acronym

[---]\*

### URL of the trial

**<https://www.klinikum.uni-heidelberg.de/Gynaekologische-Psychologie.139867.0.html>**

### Brief Summary in Lay Language

**Endometriosis is a common, gynecological, inflammatory disorder defined by the presence of benign but metastatic endometrial tissue implants outside of the uterus. Endometriosis is often associated with severe dysmenorrhea, pelvic pain, pain during sexual intercourse, and infertility. Aim of this study is to explore the relationship between partnership, experience of pain and stress in 120 women with and without endometriosis and their partners.**

### Brief Summary in Scientific Language

**The prevalence of pelvic endometriosis is about 10-15% in the general population, whereas it approaches about 70% in women treated in fertility clinics. There is currently no cure for endometriosis and successful treatment of endometriosis-associated symptoms typically requires medical as well as surgical interventions. With the prognosis of endometriosis being indefinite, this can be an additional stress factor for affected patients and their partners. Endometriosis presents itself with diverse symptoms of varying severity, which can considerably limit the quality of life of affected women.**

**Aim of this study is to explore the relationship between partnership, pain and stress in women with and without endometriosis and their partners. Furthermore, the impact of variables such as sexuality, wish for a child, social support, depression, anxiety and spirituality in relation to endometriosis will be investigated.**

**The study is planned as a quantitative cross-sectional study with a total sample size of N = 120 women and their partners. All patients undergoing laparoscopy for organic findings during their treatment at the Department of Gynecological Endocrinology and Fertility Disorders at the University Hospital Heidelberg can take part in the study. Psychometric parameters are recorded via questionnaires.**

### Do you plan to share individual participant data with other researchers?

[---]\*

## Description IPD sharing plan

[---]\*

## Organizational Data

- DRKS-ID: **DRKS00014362**
- Date of Registration in DRKS: **2018/03/29**
- Date of Registration in Partner Registry or other Primary Registry: [---]\*
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **S-301/2016 , Ethik-Kommission I der Medizinischen Fakultät Heidelberg**

## Secondary IDs

## Health condition or Problem studied

- ICD10: **N80 - Endometriosis**
- ICD10: **N97 - Female infertility**

## Interventions/Observational Groups

- Arm 1: **Investigation of women with endometriosis and wish for a child (E+C+) plus their partners after laparoscopy at Heidelberg University Hospital or Innsbruck University Hospital. The questionnaire comprises items to partnership, experience of pain, psychological stress, sexuality, wish for a child, social support, anxiety, depression and spirituality.**
- Arm 2: **Investigation of women with endometriosis and no wish for a child (E+C-) plus their partners after laparoscopy at Heidelberg University Hospital or Innsbruck University Hospital. The questionnaire comprises items to partnership, experience of pain, psychological stress, sexuality, wish for a child, social support, anxiety, depression and spirituality.**
- Arm 3: **Investigation of women with no endometriosis and wish for a child (E-C+) plus their partners after laparoscopy at Heidelberg University Hospital or Innsbruck University Hospital. The questionnaire comprises items to partnership, experience of pain, psychological stress, sexuality, wish for a child, social support, anxiety, depression and spirituality.**

## Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Other**
- Blinding: [---]\*
- Who is blinded: [---]\*
- Control: **Other**
- Purpose: **Diagnostic**
- Assignment: **Other**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

### Primary Outcome

**One-time questionnaire investigation on partnership, experience of pain and stress in women affected by endometriosis and their Partners after laparoscopy at University Hospital Heidelberg or University Hospital Innsbruck. The questionnaire was put composed from the following questionnaires: Endometriosis Health Profile (EHP-5), Deutscher Schmerzfragebogen (German Pain Questionnaire, DSF), Perceived Stress Scale (PSS), Depression Anxiety Stress Scales (DASS), Questions from Swiss Household Panel (SHP), Screen-IVF, Female Sexual Function Index (FSF) and Spiritual and Religious Attitudes in Dealing with Illness (SpREUK)**

### Secondary Outcome

**not applicable**

### Countries of recruitment

- DE **Germany**
- AT **Austria**

### Locations of Recruitment

- University Medical Center **Abteilung für Gynäkologische Endokrinologie und Fertilitätsstörungen der Universitäts-Frauenklinik Heidelberg , Heidelberg**
- University Medical Center **Universitätsklinik für Gynäkologische Endokrinologie und Reproduktionsmedizin, Department Frauenheilkunde, Innsbruck, Österreich**

### Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2016/09/30**

Planned/Actual: **Actual**

(Anticipated or Actual) Date of First Enrollment: **2016/09/30**

- Target Sample Size: **240**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

### Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **45 Years**

### Additional Inclusion Criteria

**All women aged 18 to 45 years (plus their partners) undergoing laparoscopy for organic findings during their treatment at the Department of Gynecological Endocrinology and Fertility Disorders at the University Hospital Heidelberg / at University Hospital Innsbruck can take part in the study.**

### Exclusion criteria

**Exclusion criteria are refusal of participation and/or insufficient knowledge of german language as well as presence of life-threatening diseases.**

### Addresses

#### ■ Primary Sponsor

**Institut für Medizinische Psychologie, Universitätsklinikum Heidelberg  
Ms. Prof. Dr. Beate Ditzen  
Bergheimer Str. 20  
69115 Heidelberg  
Germany**

Telephone: **+49-(0)6221-568150**

Fax: **+49-(0)6221-565303**

E-mail: **beate.ditzen at med.uni-heidelberg.de**

URL: **<https://www.medpsych.uni-hd.de/>**

#### ■ Contact for Scientific Queries

**Institut für Medizinische Psychologie, Universitätsklinikum Heidelberg**

### **Contact for Scientific Queries**

**Institut für Medizinische Psychologie, Universitätsklinikum Heidelberg**

**Ms. M.Sc. Psych. Maren Schick**

**Bergheimer Str. 20**

**69115 Heidelberg**

**Germany**

Telephone: **+49- (0)6221-568148**

Fax: **+49- (0)6221-565303**

E-mail: **maren.schick at med.uni-heidelberg.de**

URL: **<https://www.medpsych.uni-hd.de/>**

### ■ **Contact for Public Queries**

**Institut für Medizinische Psychologie, Universitätsklinikum Heidelberg**

**Ms. M.Sc. Psych. Maren Schick**

**Bergheimer Str. 20**

**69115 Heidelberg**

**Germany**

Telephone: **+49- (0)6221-568148**

Fax: **[---]\***

E-mail: **maren.schick at med.uni-heidelberg.de**

URL: **<https://www.medpsych.uni-hd.de/>**

### ■ **Collaborator, Other Address**

**Universitätsklinik für Gynäkologische Endokrinologie  
und Reproduktionsmedizin, Department Frauenheilkunde**

**Ms. Prof. Dr. Bettina Toth**

**Anichstraße 35**

**6020 Innsbruck**

**Austria**

Telephone: **050 504 23068**

Fax: **[---]\***

E-mail: **info at kinderwunsch-zentrum.at**

URL: **[www.kinderwunsch-zentrum.at](http://www.kinderwunsch-zentrum.at)**

## **Sources of Monetary or Material Support**

### ■ **Institutional budget, no external funding (budget of sponsor/PI)**

**Institut für Medizinische Psychologie Zentrum für Psychosoziale Medizin  
(ZPM) Universitätsklinikum Heidelberg**

**Ms. Prof. Dr. Beate Ditzen**

**Bergheimer Str. 20**

**69115 Heidelberg**

**Germany**

---

**Institutional budget, no external funding (budget of sponsor/PI)**

**Institut für Medizinische Psychologie Zentrum für Psychosoziale Medizin  
(ZPM) UniversitätsKlinikum Heidelberg  
Ms. Prof. Dr. Beate Ditzen  
Bergheimer Str. 20  
69115 Heidelberg  
Germany**

Telephone: [---]\*

Fax: [---]\*

E-mail: **beate.ditzen at med.uni-heidelberg.de**

URL: **<https://www.medpsych.uni-hd.de/>**

## Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2018/08/14**

## Trial Publications, Results and other documents

\* This entry means the parameter is not applicable or has not been set.

\*\*\* This entry means that data is not displayed due to insufficient data privacy clearing.