Trial Description

Title

cENZIAN versus ENZIAN – An observational multicenter study on the prediction of a preoperative to an intraoperative ENZIAN classification for endometriosis surgery.

Trial Acronym

cENZIAN-Trial

URL of the trial

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Brief Summary in Lay Language

This study should serve as a review whether the results of a postoperative performed disease classification ("ENZIAN" classification) are predictable by the preoperative application of this classification ("cENZIAN") in patients with endometriosis. This study is important because in recent years, the importance of preoperative diagnostics in deep infiltrating endometriosis has increased significantly. The planned number of participants is 900-1000 patients. The study is a pure observational study without risk for the study participants.

Brief Summary in Scientific Language

This multicenter study should serve as a review whether the results of a postoperative performed disease classification ("ENZIAN" classification) are predictable by the preoperative application of this classification ("cENZIAN") in patients with endometriosis. This study is important because in recent years, the importance of preoperative diagnostics in deep infiltrating endometriosis has increased significantly. The study is to be classified as a non-interventional method study (classification of the cENZIAN classification as a new diagnostic method without any risk for the study participants). The planned number of participants is 900-1000 patients.

Organizational Data

- DRKS-ID: **DRKS00013614**
- Date of Registration in DRKS: **2017/12/22**
- 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.: **1002/2017 , Ethikkommission des Landes Oberösterreich**

Secondary IDs

Health condition or Problem studied

- ICD10: **N80 - Endometriosis**

Interventions/Observational Groups

- Arm 1: **In patients with a planned endometriosis surgery, the common diagnostic measures are carried out routinely (depending on the use or need: palpation/speculum, ultrasound, MRI or further imaging), regardless of the study. The responsible physician will then fill out the section "cENZIAN" in the questionnaire for each diagnostic measure. At the end of the surgical procedure, the surgeon records his intraoperative impressions under the heading "ENZIAN". This concludes the study participation of the patient.**

Characteristics

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

Primary Outcome

This study should serve as a review whether the results of a postoperative performed disease classification ("ENZIAN" classification) are predictable by the preoperative application of this classification ("cENZIAN") in patients with endometriosis.

Secondary Outcome

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Countries of recruitment

- AT **Austria**
- DE **Germany**
- CZ **Czech Republic**
- CH **Switzerland**

Locations of Recruitment

- University Medical Center **Kepler Universitätsklinikum, Linz**
- University Medical Center **Universitätsklinik für Frauenheilkunde, Bern**
- University Medical Center **Universitätsklinikum Tübingen, Tübingen**
- Medical Center **Landesklinikum Melk, Melk**
- Medical Center **UPMD, Prag**
- University Medical Center **Universitätsklinikum Münster, Klinik für Frauenheilkunde und Geburtshilfe, Münster**
- Medical Center <style fontName='DejaVu Sans' isBold='true'>St.Anna Hospital Herne, Klinik für Frauenheilkunde & Geburtshilfe, Herne</style>
- University Medical Center **Universitätsklinikum Carl Gustav Carus an der Technischen Universität Dresden, Dresden**
- University Medical Center **Medizinische Universität Innsbruck, Department Frauenheilkunde, Universitätsklinik für Gynäkologische Endokrinologie und Reproduktionsmedizin, Innsbruck**
- Medical Center **AGAPLESION MARKUS KRANKENHAUS, Frankfurt, Klinik für Gynäkologie und Geburtshilfe, Frankfurt a.M.**
- University Medical Center **Universitätsklinikum Freiburg, Klinik für Frauenheilkunde, Freiburg**
- Medical Center **Marien Hospital Witten, Frauenklinik, Witten**
- University Medical Center **Universitätsklinikum Ulm, Ulm**
- University Medical Center **Medizinische Hochschule Hannover (MHH), Klinik Frauenheilkunde und Geburtshilfe, Hannover**
- Medical Center **Evangelisches Krankenhaus Bethesda Mönchengladbach, Mönchengladbach**
- Medical Center **St. Johannes Hospital, Dortmund**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2018/01/16**
- Target Sample Size: **900**
- Monocenter/Multicenter trial: **Multicenter trial**

Planned/Actual: **Actual**

(Anticipated or Actual) Date of First Enrollment: **2018/01/16**

Target Sample Size: **900**

Monocenter/Multicenter trial: **Multicenter trial**

- National/International: **International**

Inclusion Criteria

- Gender: **Female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

• Informed consent to participate in the study after preceding written and verbal information
• Suspected or confirmed endometriosis with planned surgery within 6 months
• Ability to consent
• Age > 18 years

Exclusion criteria

Inapplicability of the diagnostic procedures routinely provided for preoperative endometriosis-specific knowledge acquisition (e.g. gynecological examination, ultrasound or other imaging)

Addresses

- **Primary Sponsor**

Kepler Universitätsklinikum
4020 Linz
Austria

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

- **Contact for Scientific Queries**

Kepler Universitätsklinikum - Universitätsklinik für Gynäkologie, Geburtshilfe und Gyn. Endokrinologie
Mr. Dr. Simon-Hermann Enzelsberger
Krankenhausstraße 26-30
4020 Linz

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URL: **https://www.kepleruniklinikum.at/versorgung/kliniken/gynaekologie-geburtshilfe-und-gyn-endokrinologie**

- **Contact for Public Queries**

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URL: **https://www.kepleruniklinikum.at/versorgung/kliniken/gynaekologie-geburtshilfe-und-gyn-endokrinologie**

Sources of Monetary or Material Support

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

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Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting complete, follow-up continuing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

- Approval of ethics comm. (mandatory for transfer to Studybox) **Positives Ethikvotum**

** 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.*