Trial Description

Title

Topical EMLA-patch for postoperative wound pain after gynecological laparoscopy

Trial Acronym

EMGYN

URL of the trial

[---]*

Brief Summary in Lay Language

Aim of this study is to analyse the effectivity of anesthtic patches (patches containing anesthetics) on incisional pain after laparoscopic surgery. Patients undergoing surgery due to gynecologic reasons are going to be examined. The priniciple aim of this study is postoperative pain these anesthetic patches compared to conventional patches. Further study aims are the evaluation of the length of hospital stay and need of additional medication for pain relief. Hence either anesthetic patches or conventional patches are installed on the incisions after suergery. The amount of pain after surgery will be analysed with a standardised questionnaire.

Brief Summary in Scientific Language

Aim of this study is to analyse the effectivity of EMLA-patches on incisional pain after laparoscopic surgery. Patients undergoing surgery due to gynecologic reasons are going to be examined. The priniciple aim of this study is postoperative pain using EMLA-patches compared to conventional patches. Further study endpoints are length of hospital stay and need of additional medication for pain relief. Hence either EMLA-patches or conventional patches are installed on the incisions after suergery. The amount of pain after surgery will be analysed with a standardised questionnaire (Short-Form McGill Pain Questionnaire (MPQ-SF)).

Organizational Data

- DRKS-ID: **DRKS00003869**
- Date of Registration in DRKS: **2012/05/04**
- 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.: **2012-252N-MA , Medizinische Ethik-Kommission II Medizinische Fakultät Mannheim der Universität Heidelberg**

Secondary IDs

Health condition or Problem studied

- ICD10: **D25.9 - Leiomyoma of uterus, unspecified**
- ICD10: **R10.3 - Pain localized to other parts of lower abdomen**
- Free text: **Other gynaecologic diseases in which a laparoscopy has to be performed.**

Interventions/Observational Groups

- Arm 1: **Study collective: EMLA-patch**
- Arm 2: **Control collective: placebo (conventional patch)**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **Single blind**
- Who is blinded: **[---]***
- Control: **Placebo**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Priniciple aim of this study is postoperative pain using EMLA-patches compared to conventional patches (controlled by the standardized Questionaire"Short form Mc Gill Pain Questionaire").

Secondary Outcome

Further study endpoints are length of hospital stay and need of additional medication for pain relief.

Further study endpoints are length of hospital stay and need of additional medication for pain relief.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Frauenklinik, Mannheim**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2012/05/15**
- Target Sample Size: **120**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

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

Additional Inclusion Criteria

patients with laparoscopy

Exclusion criteria

allergy against amide-anesthetics

Addresses

- **Primary Sponsor**

  Universitätsklinikum Mannheim

Primary Sponsor

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Sources of Monetary or Material Support

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

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Status

- Recruitment Status: **Recruiting planned**
- Study Closing (LPLV): **[---]***

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.*