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Abdominal keyhole surgery with spinal anesthesia

Submission date	Recruitment status	[_] Prospectively registered
30/10/2020	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/07/2024	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
03/09/2024	Urological and Genital Diseases	

Plain English summary of protocol

Background and study aims
Pelvic surgery is performed with the patient in the Trendelenburg position (lying on the operating table which is angled so that the head is lower than the feet) and with high intraabdominal CO_2 pressure in order to move the intestines out of the surgical field and to create an optimal view for the surgical team.
The aim of this study is to assess the effectiveness and safety of laparoscopic surgery with spinal anesthesia in the Trendelenburg position with different pressures of CO_2. What is the best protocol in terms of risk and comfort for the patient and the surgeon?

Who can participate?
Women due to undergo laproscopic surgery

What does the study involve?
The surgery is carried out as usual. Different pressures of CO_2 are used to investigate the effect on ease of performing the surgery and the level of risk to the patient.

What are the possible benefits and risks of participating?
None

Where is the study run from?
Medline Clinics (Uzbekistan)

When is the study starting and how long is it expected to run for?
December 2018 to October 2020

Who is funding the study?
ESTHER Switzerland – Network for the promotion of Institutional Health Partnerships (IHP)

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Laparoscopic surgery with spinal anesthesia: a prospective observational study

Study objectives
The primary objective is to evaluate the feasibility of laparoscopic surgery of the pelvic organs under loco-regional anesthesia. Patient and surgeon comfort are analyzed by using different parameters of the laparoscopic procedure (degree of Trendelenburg inclinision, pressure of CO2-pneumoperitoneum, type of operation, length of operation). Side effects will be recorded.
The secondary objective is to analyse the recovery of the patient after surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/12/2018, Ethical Committee at Tashkent Medical Academy, Urgench branch, Uzbekistan (14, H.Olimjon str, Urgench, Khorezm region, 220100, Uzbekistan; +998 (0) 995649170; no email provided), ref: 01/2016

Study design
Prospective observational study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Gynecological diseases in the pelvis

Interventions
Laparoscopic surgery was performed for pelvic diseases using spinal anesthesia and with the patient in the Trendelenburg position, using different CO_2 pressures for pneumoperitoneum. Without or with very low CO_2 pressures the uterus was pushed with a cervical manipulator

forceps towards the abdominal wall in order to view the organs of the pelvis. No additional medicine was used intravenously. Pneumoperitoneum was generated with CO_2 gas between 4 to 14 mmHg.

Intervention Type
Procedure/Surgery

Primary outcome measure
Measured using a survey before, during and post surgery:
1. Comfort of the patient and the surgeon
2. Pain during the operation
3. Feasibility of performing the surgery
4. Questions about satisfaction (changes or symptoms pre-and post-operatively, time of recovery, satisfaction with information, improvement in well being, recommending the operation)

Secondary outcome measures
Measured using self-report on a 0–10 scale (0=minimum, 10=maximum impairment) before, during and post surgery:
1. Symptoms (pain, postoperative symptoms)
2. Side effects (headache, nausea)
3. Quality of life (felt tired/drained/lacking energy, felt irritable/snappy, felt depressed/tearful, general evaluation of health, change in body perception)

Overall study start date
02/12/2018

Completion date
30/10/2020

Eligibility

Key inclusion criteria
1. Women who will undergo laparoscopic surgery in the lower abdomen
2. Minimum follow up of 6 months

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
100

Total final enrolment
93

Key exclusion criteria
1. Contraindication for loco-regional anesthesia
2. Do not consent to complete the questionnaire

Date of first enrolment
09/01/2019

Date of final enrolment
23/05/2019

Locations

Countries of recruitment
Uzbekistan

Study participating centre
Medline Clinics
14, H.Olimjon str
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Sponsor information

Organisation
ESTHER

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Sponsor type
Other

Website
https://www.esther-switzerland.ch/

Funder(s)

Funder type
Government

Funder Name
ESTHER Switzerland – Network for the promotion of Institutional Health Partnerships (IHP)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
30/12/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		14/06/2024	28/08/2024	Yes	No