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Study of the effectiveness and safety of LigaSure™ in hysterectomy

Submission date
11/11/2016

Recruitment status
No longer recruiting

Registration date
21/12/2016

Overall study status
Completed

Last Edited
15/12/2016

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English Summary
Background and study aims
A hysterectomy is a surgical procedure to remove the womb (uterus). They are used to treat conditions that affect the female reproductive system, such as long-term pelvic pain and cancer. Natural orifice transluminal endoscopic surgery (NOTES) is a surgical technique in which the surgery is performed by passing a tube through a natural orifice (such as the mouth, urethra or anus) in order to perform the surgery. Virginal hysterectomy involves removal of the uterus via a natural orifice, that is, via the vagina. The use of vaginal hysterectomy is a surgical option for women as a component for pelvic surgery for pelvic prolapse, and also in benign conditions such as fibroids and abnormal bleeding. Vaginal hysterectomy has shown benefits over abdominal hysterectomy such as faster recovery and fewer fever episodes post-operatively. This study is to compare the safety and effectiveness of two different devices used in vaginal hysterectomy.

Who can participate?
Women aged 35 and over who are scheduled to undergo a hysterectomy.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group undergo a hysterectomy using the LigaSure™ tissue fusion system device. This uses an electrical current to seal the cuts made during surgery with the patient's own tissue. Those in the second group undergo a hysterectomy using Wolf Eragon bipolar forceps 5mm, which involves creating a seal using special forceps. The time taken to perform each procedure is recorded and blood loss measured. In addition, the complication rate in each group is assessed.

What are the possible benefits and risks of participating?
There are no guaranteed benefits of taking part however the outcome of the study may help the investigators to have a better understanding of LigaSure™ and benefit future patients undergoing transvaginal NOTES hysterectomy with LigaSure™. There are no notable risks of participating other than the general risks associated with undergoing a hysterectomy, such as bleeding, infections, injury to surrounding organs and structures, incontinence, constipation, and impact on sexual function.

Where is the study run from?
Chang Gung Memorial Hospital, Linkou branch (Taiwan)

When is the study starting and how long is it expected to run for?
October 2010 to August 2014

Who is funding the study?
Covidien Private Limited (Singapore)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
11-EBD-TW-VS-AC-00

Study information

Scientific Title
An Investigational Study of the Effectiveness and Safety of the LigaSure™ Tissue Fusion System in Hysterectomy via Transvaginal Natural Orifice Transluminal Endoscopic Surgery (NOTES)

Acronym
NOTES

Study hypothesis
The aim of this study is to evaluate the effectiveness of using the LigaSure™ tissue fusion system in transvaginal hysterectomy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Chang Gung Medical Foundation Institutional Review Board, 09/04/2013, ref: (102) CGMF-TP No. 203

Study design
Prospective single-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet

Condition
Transvaginal hysterectomy

Interventions
Patients who sign an informed consent will be enrolled in the study upon verification that all inclusion and exclusion criteria have been met. Patients' demographics and medical histories will be collected and their vital signs will be measured at screening visit. Eligible patients will be randomized to one of two groups 24 hours before the surgery using envelope randomisation in a 1:1 ratio.

Intervention group: Participants undergo Hysterectomy via Transvaginal Natural Orifice Transluminal Endoscopic Surgery (NOTES) will be performed using LigaSure™ tissue fusion system. This involves hysterectomy via a natural orifice. This vaginal hysterectomy can create autologous seals from the patient's own tissue without use of clips or sutures, and reduce intraoperative blood loss in surgery. The bipolar instrument generates highfrequency electrical current that passes through tissue which is clamped between two electrode pads. As the current is delivered, it passes through and heats the tissues. The heating effects cut, coagulate, desiccate, or cauterize tissue.

Control group: Participants undergo Hysterectomy via Transvaginal Natural Orifice Transluminal Endoscopic Surgery (NOTES) will be performed using Wolf Eragon bipolar forceps 5mm. This involves hysterectomy via a natural orifice. The bipolar forceps are applied transvaginally to coagulate and cut the uterosacral ligament.

For all participants, on post-operative day 1, vital signs, routine laboratory tests and stress hormones will be assessed on the following day (at least 12 hours after the surgery). At hospital discharge, vital signs and pain score will be assessed. Moreover, information on surgery-related costs, hospitalization stay and costs, concomitant medications usage and costs will be collected. All adverse events, adverse device events, unanticipated adverse device events and complications experienced by the subjects during the procedure and until their discharge from hospital will be recorded. At post-operative day 30, vital signs, concomitant medications usage and costs, and all adverse events and complications after the discharge will be collected.

Intervention Type
Device

Primary outcome measure
Operative time is measured as the duration from the time of skin incision to the time of final suture in skin closure during surgery.

Secondary outcome measures
1. Operative blood loss is measured by weighing the sponges and gauze pads used during the operation, and measuring the drainage containers/suction bottle post-operatively
2. Length of hospital stay is assessed by measuring the time between hospital admission and discharge
3. Surgical complications (e.g. bleeding, hematoma, micturition, abnormal defecation, decreased appetite, fatigue, myalgia and pain), will be assessed by the investigator and recorded in the CRF as adverse events. It will be assessed from operation day till post-operation day 30
4. Surgery costs will be calculated by capturing of cost in the CRFs. The cost may include (but not limited to), surgery cost and instruments cost, anaesthesia used (duration and cost), post-operative analgesic used (duration and cost), and hospitalization cost. Self-payment, co-payment, and insurance coverage of the surgery information will also be captured in the CRF.
5. Post-operative pain intensity will be assessed by the visual analogue scale (VAS) at least twice daily by the patient until the patient is discharged from the hospital
6. Blood samples will be taken at Pre-Op (1 day before operation, 15 mL) and Post-Op Day 1 (10 mL) for routine safety laboratory tests and stress hormones. The safety laboratory tests, including hematology tests (red blood cells count, white blood cells count and its differentials, platelet count, hemoglobin and hematocrit) and biochemistry tests (AST, ALT, bilirubin, creatinine, total protein and BUN), will be assessed by the hospital central laboratory. Both hematology and biochemistry tests will be assessed before the surgery; however, only hematology tests will be assessed at the next day after the surgery. Stress hormones or cytokine levels including interleukin-6 (IL-6), interleukin-1 beta (IL-1B), Tumor necrosis factor - alpha (TNF-a) and C-reactive protein (CRP), will be assessed before the surgery and at the next day after the surgery by the hospital central laboratory or the designated laboratory. Stress hormones will be measured to assess surgical stress, i.e. tissue trauma and inflammatory response.
7. Conversion rate to conventional laparoscopy or laparotomy is measured by the proportion of converted patients within the treatment group. Patients who are randomized but undergo the surgery without the designated device or with other kind of vessel sealing device, and/or converted to conventional laparoscopy or laparotomy were considered as converted patients.

Overall study start date
19/10/2012

Overall study end date
22/08/2014

Eligibility

Participant inclusion criteria
1. Female patients 35 years of age or older
2. Scheduled to undergo a transvaginal NOTES hysterectomy
3. Willing to provide informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
72 patients

Participant exclusion criteria
1. Multiple abdominal surgery, except caesarean section
2. History of coagulation disorder
3. History of liver and renal dysfunction within 6 months prior to inclusion into the study
4. Severe inflammatory diseases
5. Malignancy
6. Electrosurgery contraindicated
7. Hypersensitivity to or unable to tolerate general anesthesia or analgesic
8. Those participating any clinical trials within 3 months prior to the intervention
9. Not suitable for surgical intervention at the discretion of the investigator

Recruitment start date
05/08/2013

Recruitment end date
14/04/2014

Locations

Countries of recruitment
Taiwan

Study participating centre

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Sponsor information

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Covidien Private Limited

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Sponsor type
Industry

ROR
https://ror.org/01y0zfy93

Funder(s)

Funder type
Industry

Funder Name
Covidien Private Limited

Results and Publications

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

Intention to publish date
31/03/2017

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Director, Clinical Affairs of Covidien Private Limited (A Medtronic Company) at Lawrence.Lee@covidien.com

IPD sharing plan summary

Available on request