ISRCTN63952470 https://doi.org/10.1186/ISRCTN63952470

Comparing the impact of dienogest with short term gonadotropin-releasing hormone (GnRH) analogue usage in endometriosis prior to laparoscopic cystectomy.

Submission date
31/05/2016

Recruitment status
No longer recruiting

Registration date
27/07/2016

Overall study status
Completed

Last Edited
29/07/2016

Condition category
Urological and Genital Diseases

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

Plain English summary of protocol

Background and study aims
Endometriosis is a common medical condition where tissue that behaves like that found in the womb (the endometrium) can be found outside of the womb. These pieces of tissue can be found in many different areas of the body, including, for example, the ovaries and fallopian tubes, the bowel and the bladder. Endometriosis is a debilitating disease, which can cause a chronic (long lasting) and unbearable pelvic pain. 10-15% of women of reproductive age group suffer from pelvic endometriosis and 50% of infertile women is said to be suffering from endometriosis. Treatment include medical and surgical interventions aiming to alleviate these symptoms and to improve fertility rate. Drug therapy includes pain killers, gonadotrophin-releasing hormone (GnRH) analogues, progestin and now, dienogest. GnRH will cause a state of hypoestrogenemia (a menopause-like state) which lead to an easing of the pain suffered. However, although it is an effective treatment, its prolonged used is associated with significant symptoms of hypoestrogenism (for example, hot flashes, headaches, lower than usual sex drive), and decreased bone mineral density, which could lead to brittle bones (secondary osteoporosis). Dienogest in the other hand is a 4th generation selective progestin. It stops ovulation, and prevents the lining of the womb and any endometriosis tissue outside of the womb from growing quickly. Surgery can be used to remove endometriosis tissue. The gold standard is laparoscopic cystectomy. However, the side effects of this surgery has been questioned. Although it does reduce the risk of recurrence, it is associated with removal of ovarian tissue together with the wall, leading to a loss of follicles and postsurgical ovarian failure (3%). The aim of this study is to investigate the result of a combined medical and surgical treatment for endometriosis.

Who can participate?
Women with endometriosis with a cyst that is to be removed via a laparoscopic cystectomy.

What does the study involve?
Participants are randomly allocated to one of three groups. Those on group 1 are not given any

treatment prior to a laparoscopic cystectomy. Those in group 2 are given a single dose of a GnRH analogue 1 month before surgery. Those in group 3 are given dienogest once a day for 30 days before undergoing surgery. After the surgery, all participants are assessed to determine the success of the treatment and their overall satisfaction of the care they receive.

What are the possible benefits and risks of participating?
They may be no direct benefits to taking part in the study, but the results may help improve the treatment or management of the condition for other patients. Possible side effects include nausea, vomiting, breast engorgement, irregular menstrual bleed, abdominal cramps, flatulence, sleep disorder, loss of libido (sex drive), altered mood and migraine headaches.

Where is the study run from?
University Malaya Medical Centre (Malaysia)

When is the study starting and how long is it expected to run for?
June 2016 to June 2017

Who is funding the study?
University Malaya Medical Centre (Malaysia)

Who is the main contact?
Dr Aizura Syafinaz Ahmad Adlan

Contact information

Type(s)
Scientific

Contact name
Dr Aizura Syafinaz Ahmad Adlan

Contact details
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47400

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NMRR-16-317-29736

Study information

Scientific Title
Comparing the impact of DIenogest with short term GnRH analogue usage in women with Endometriosis prior to laparoscopic Cystectomy: a randomised controlled trial

Acronym
DIGEC

Study objectives
Preoperative usage of dienogest will give better surgical outcomes compared to preoperative GnRH usage, for women undergoing laparoscopic cystectomy for endometriomas.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Malaya Medical Centre Medical Ethics Committee, 18/01/2016, ref: MECID.NO: 20159-1645

Study design
Interventional randomised controlled trial, single centre.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Endometriosis

Interventions
Prior to the initiation of the study, blood will be taken for series of investigations- for AMH, Ca 125, FSH/LH level. Transvaginal ultrasound will be performed to look for antral follicular count.

Participants are allocated into one of three groups:
Group 1: No pretreatment administered pre-operatively (control group)
Group 2: single dose of GnRH analogue will be given (s/c lucrin 3.75mg) 1 month prior to the surgery date
Group 3: oral dienogest 2mg daily will be given to be taken for 30 days

A laparoscopic cystectomy will be performed 1 month after the initiation of the above treatment. After the operation all participants are also assessed regarding overall satisfaction of the treatment that they have received.

Randomisation is made by computerised block randomisation. Patient will pick 1 out of 3 sealed envelope the patient is not blinded by the treatment that they will receive, the surgeon however will not be made aware of the treatment received by their patient.

Intervention Type
Supplement

Primary outcome measure
1. Feasibility of cyst extraction intraoperatively (rating: easy/moderate/difficult)
2. Duration of surgery (recorded in minutes)
2. Patient satisfaction with the post operative pain relief using a visual analogue score

Secondary outcome measures
Intraoperative blood loss in millilitres. Outcome will be retrieved from the surgical notes, anaesthetists notes on or after hospital discharge.

Overall study start date
01/06/2016

Completion date
30/06/2017

Eligibility

Key inclusion criteria
1. Patients with cyst suspicious of endometrioma
2. Cyst measures > 4 cm
3. Planned for a laparoscopic cystectomy

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
120

Key exclusion criteria
Patients with cysts suspicious of malignancy.

Date of first enrolment
01/06/2016

Date of final enrolment
30/06/2017

Locations

Countries of recruitment
Malaysia

Study participating centre
University Malaya Medical Centre
Lembah Pantai
Kuala Lumpur
Malaysia
50603

Sponsor information

Organisation
University Malaya Medical Centre, University of Malaya.

Sponsor details
Lembah Pantai
Kuala Lumpur
Malaysia
50603

Sponsor type
University/education

ROR
https://ror.org/00vkrxq08

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Malaya Medical Centre

Results and Publications

Publication and dissemination plan
Publication intended for any ISI-ranked journal. Dissemination of results for usage in daily clinical practice

Intention to publish date
31/08/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		22/07/2016	29/07/2016	No	Yes