

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	<input type="checkbox"/> Prospectively registered
Registration date 27/07/2016	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 29/07/2016	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

104, SS22/2

Damansara Jaya

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Malaysia

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