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Can the levels of a cell signalling factor in menstrual blood be used as a test for endometriosis?

Submission date
02/05/2023

Recruitment status
No longer recruiting

Registration date
30/06/2023

Overall study status
Completed

Last Edited
08/01/2024

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Endometriosis is a benign disorder that is generally defined as the presence of endometrial glands and stroma outside their normal location. TGF-β1 is found in stromal cells and its expression is increased in epithelial cells of endometriotic cysts. Endometriosis diagnosis takes a long time, so new markers are needed to diagnose endometriosis. This study aims to determine the diagnostic value of TGF-β1 in menstrual blood for diagnosing endometriosis.

Who can participate?
Patients aged between 25–35 years old with suspected endometriosis

What does the study involve?
Diagnostic tests to compare TGF β1 levels in the menstrual blood of patients with suspected endometriosis.

What are the possible benefits and risks of participating?
The benefits are having a free TGF test and the results will present an important part of finding new screening for endometriosis. Social risks include embarrassment when collecting samples of blood.

Where is the study run from?
The Department of Obstetrics and Gynecology Dr Mohammad Hoesin General Hospital/Faculty of Medicine, Sriwijaya University, Palembang (Indonesia)

When is the study starting and how long is it expected to run for?
July 2019 to December 2020

Who is funding the study?
Investigator and Sriwijaya University initiated and funded (Indonesia)

Who is the main contact?
Mrs Excellena Nasrul, excellena90@gmail.com

Contact information

Type(s)
Principal Investigator

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Scientific

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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
Diagnostic test of transforming growth factor-beta 1 (TGF-β1) in menstrual blood with endometriosis

Acronym
DTTMBE

Study objectives
TGF β1 level has a very good diagnostic value in establishing an endometriosis diagnosis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/08/2019, Ethical Committee of Mohammad Hoesin Central General Hospital and Faculty of Medicine Sriwijaya University (Jalan Jenderal Sudirman Km 3,5, Palembang, Indonesia, 30126; +62 0711 352342; tu@unsri.ac.id), ref: 330/kepkrsmhfkunsri/2019

Study design
Interventional study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Diagnostic

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

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

Interventions
Married women with suspected endometriosis aged from 25–35 years old (>35 years until before menopause), who agree to undergo operative laparoscopy, participate in the study and signed an informed consent will be included.

Patients with suspected malignancy, chronic inflammation, diabetic retinopathy, pregnancy, and use of GnRH agonists before laparoscopy will be excluded from this study. In addition, the criteria for dropping out in this study were patients with blood cell lysis on examination. Withdrawal criteria in this study are subjects who refused to continue the study. Samples were collected by doing consecutive sampling.

All patients who will be included in this study have anamnesis (name, age, address, parity, Last Menstrual Period (LMP), previous medical history, previous use of contraception, history of drug abuse), physical examination (general condition, blood pressure, pulse rate, respiration rate, temperature, body height, and weight). Menstrual blood samples will be collected before surgery when the patient is menstruating for the first three days and obtained through storage in the menstrual cup. Menstrual blood samples were immediately taken to the laboratory and tested for TGF β1 expression by the quantitative sandwich enzyme immunoassay method. To prepare reagents and samples, enter 50μL of assay diluent RD1-73 into each well (plate has been coated with anti-TGF β1), and add 50μL of standard, control, and activated sample to each well containing the assay diluent. Then, the procedure was continued by incubating for 2 hours, rinsing, and washing 4 times using a washing buffer, adding 100μL of the conjugate, and incubating again for 2 hours, rinsing, and washing 4 times using a washing buffer, and adding 100μL of substrate solution and incubating for 30 minutes. It should be noted to keep away from light, add 100μL of the reaction-stopping solution, and read at a wavelength of 450 nm for 30 minutes. The correction wavelength is 540 or 570 nm. Furthermore, examiners should plot the standard curve and estimate the sample concentration against the curve.

Laparoscopy was performed by a Reproductive Endocrinology Fertility consultant to confirm the diagnosis and degree of endometriosis. The intraoperative findings were followed by a histopathological examination to confirm the diagnosis of endometriosis. After the data were collected, statistical analysis was performed.

Intervention Type
Procedure/Surgery

Primary outcome measure
Mean TGF β1 level in menstrual blood measured using enzyme-linked immunosorbent assay (ELIZA) during the first three days of menstruation

Secondary outcome measures
Diagnostic accuracy of TGF β1 measured using the laparoscopy outcome of endometriosis recorded in patient medical notes at one timepoint

Overall study start date
01/07/2019

Completion date
30/12/2020

Eligibility

Key inclusion criteria
Patients with suspected endometriosis who underwent laparoscopy ranging from 25–35 years of age and >35 years until before menopause, married, agreed to undergo operative laparoscopy, agreed to participate in the study and signed an informed consent

Participant type(s)
Patient

Age group

Adult

Sex
Female

Target number of participants
58

Total final enrolment
50

Key exclusion criteria
Patients with suspected malignancy, chronic inflammation, diabetic retinopathy, pregnancy, and use of GnRH agonists before laparoscopy

Date of first enrolment
16/08/2019

Date of final enrolment
30/11/2020

Locations

Countries of recruitment
Indonesia

Study participating centre
Mohammad Hoesin Central General Hospital
Jl. Jenderal Sudirman Km 3,5
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30126

Sponsor information

Organisation
Mohammad Hoesin Central General Hospital

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Sponsor type
Hospital/treatment centre

Website
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Organisation
Sriwijaya University

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.unsri.ac.id/

ROR
https://ror.org/030bmb197

Funder(s)

Funder type
University/education

Funder Name
Universitas Sriwijaya

Alternative Name(s)
Sriwijaya University, UNSRI

Funding Body Type
Government organisation

Funding Body Subtype

Universities (academic only)

Location
Indonesia

Funder Name
Investigator initiated and funded

Results and Publications

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

Intention to publish date
30/03/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Excellena Nasrul (excellena90@gmail.com).

Sharing will be limited to secondary research purposes that fall within the scope of the research described in the original consent form
and for secondary research purposes that participants have not objected to.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		11/12/2023	08/01/2024	Yes	No