

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	<input type="checkbox"/> Prospectively registered
Registration date 30/06/2023	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 08/01/2024	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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- β 1 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- β 1 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 β 1 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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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

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

Acronym

DTTMBE

Study objectives

TGF β 1 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

Study type(s)

Diagnostic

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 β 1 expression by the quantitative sandwich enzyme immunoassay method. To prepare reagents and samples, enter 50 μ L of assay diluent RD1-73 into each well (plate has been coated with anti-TGF β 1), and add 50 μ L 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 100 μ L of the conjugate, and incubating again for 2 hours, rinsing, and washing 4 times using a washing buffer, and adding 100 μ L 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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

Palembang

Indonesia

30126

Sponsor information

Organisation

Mohammad Hoesin Central General Hospital

Organisation

Sriwijaya University

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

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