Diagnosing endometriosis using exhaled breath analysis by Electronic Nose: a pilot study

Published: 29-03-2021
Last updated: 09-04-2024

The aim of this pilot study is to determine the diagnostic value of exhaled breath analysis by eNose technology for endometriosis patients: does it detect endometriosis?

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON52727

Source
ToetsingOnline

Brief title
Endometriosis eNose pilot study

Condition

- Other condition
- Menstrual cycle and uterine bleeding disorders

Synonym
Endometriosis

Health condition

endometriose

Research involving
Human

Sponsors and support

Primary sponsor: Haaglanden Medisch Centrum
Source(s) of monetary or material Support: Breathomix (stellen benodigde apparatuur beschikbaar tegen betaling),Medisch Specialistisch Bedrijf HMC

Intervention

Keyword: Breath Tests, Electronic Nose, Endometriosis/diagnosis, Volatile Organic Compound

Outcome measures

Primary outcome

The primary outcome consist of exhaled breath profiles obtained by sampling exhaled breath using eNose technology. These profiles form a characteristic fingerprint of the Volatile Organic Compounds (VOC*s) present in exhaled breath. The profiles of both endometriosis patients and healthy controls will be analysed and compared to determine the sensitivity and specificity of the eNose technology in diagnosing endometriosis.

Secondary outcome

The sensitivity and specificity of the eNose technology in differentiating between early and advanced stages of endometriosis.

Study description

Background summary

Endometriosis is a prevalent gynaecological condition, in which inflammation and oxidative stress cause pain and fibrotic lesions, which can lead to infertility in some women. The current gold standard for diagnosing endometriosis is laparoscopic visualization of the lesions with histological confirmation. Research has been unable to identify an accurate non-invasive marker. Since the invasiveness of the current diagnostic method contributes to the diagnostic delay, which results in more severe fibrotic lesions and

irreversible damage like infertility, there is an urgent need for a non-invasive diagnostic biomarker. The inflammation and oxidative stress that is associated with endometriosis, suggests patients with endometriosis are likely to have an altered metabolic profile, which can be detected with electronic-nose (eNose) technology.

Study objective

The aim of this pilot study is to determine the diagnostic value of exhaled breath analysis by eNose technology for endometriosis patients: does it detect endometriosis?

Study design

This study is a one-center cross-sectional case-control study.

Study burden and risks

There are no risks associated with participating in this study and the burden is expected to be low. Subjects will only be required to perform a breath test similar to spirometry during a single visit to the hospital and will not be subjected to any invasive testing. The data collected in this study will not directly benefit participants, but hopefully will result in a low burden, non-invasive, diagnostic test for endometriosis in patients with clinical suspicion of endometriosis.

Contacts

Public
Haaglanden Medisch Centrum

Bronovolaan 5
Den Haag 2597 AX
NL
Scientific
Haaglanden Medisch Centrum

Bronovolaan 5
Den Haag 2597 AX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Cases:
- Aged between 18-40 years.
- (1) diagnosed with endometriosis by laparoscopy OR (2) diagnosed with deep invasive endometriosis (DIE) by MRI after positive gynecological examination and subsequent ultrasound.

Controls:
- Aged between 18-40 years.
- Conformed absence of endometriosis by laparoscopy (e.g. sterilization, extra-uterine pregnancy, diagnostic in case of infertility) or laparotomy (e.g. cesarean section).

Exclusion criteria

- Underage women (<18 years)
- Postmenopausal women or women >40 years
- Pregnancy or currently breastfeeding
- Diagnosed adenomyosis without endometriosis
- Alcohol consumption <12 hours before testing

Study design

Design

Study type: Observational non invasive

Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2022
Enrollment:	80
Type:	Anticipated

Medical products/devices used

Generic name:	Breathbase solution - Electronic nose
Registration:	No

Ethics review

Approved WMO

Date:	29-03-2021
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	16-09-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	13-09-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL74072.058.20