

Method for noninvasive diagnosis of endometriosis

Field of use

The use of panel of metabolic biomarkers for the noninvasive diagnosis of endometriosis, and to an ex vivo method for diagnosing endometriosis in a subject.

Current state of technology

The current gold standard in the present diagnostics is an invasive laparoscopy followed by histochemical analyses for pathology verification. The laparoscopy may cause complications (e.g. infections or internal bleeding), is expensive, laborious (needs time for the communication of final outcome), requires adequate and certified training of participating physicians and pathologist.

Intellectual property

Patent application filed

Developed by

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Reference

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Background

Endometriosis (ICD-10 N80) is a complex, benign neoplastic, gynecological disease with ectopic growth of endometrium-like tissue that affects around 170 million women worldwide; around 40,000 new cases are observed annually only in Germany. It manifests itself with dysmenorrhea, dyspareunia and chronic pelvic pain up to infertility. There are three main types of endometriosis: peritoneal endometriosis, ovarian endometriosis and deep infiltrating endometriosis depending on different location of ectopic endometrial tissue in the peritoneal cavity. The endometriosis can be as well manifested in a mixed form e.g. peritoneal and ovarian. Diagnosis is currently always invasive. Treatment for pain relief, prevention of recurrence, and maintenance of fertility includes nonsteroidal anti-inflammatory drugs and hormonal approaches. Due to the high individual variability and unspecific symptoms, which can also be related to other diseases, it takes an average of seven years before endometriosis is finally diagnosed. Apart from the diagnostic difficulties mentioned above, there are currently no reliable biomarkers that could predict the presence of endometriosis with high sensitivity and specificity.

Description of invention

The present invention is based on the identification and use of a panel of metabolic biomarkers for the diagnosis of endometriosis. The biomarkers are to be measured by mass spectrometry apparatus. However, instead of comparing to reference values in healthy individuals, the present invention uses selected metabolite ratios. Different combinations of metabolites like two predictors (two pairs of two metabolites) and three predictors (three pairs of two metabolites) were tested for diagnostic performance, and were successful in biostatistical evaluations. This approach has the advantage of normalization of human metabolome variability caused by ethnicity, age, nutrition, lifestyle or medication. The metabolite-based diagnosis method of the present invention provides for a cheap, fast, reliable and accurate way for diagnosing endometriosis in a subject.

Main advantages

The use of selected biomarkers results in a diagnostic score outperforming that was used so far in the diagnostics of endometriosis. Further, the assay is based on semi-invasive blood collection and a measurement on a standardised mass spectrometer. The analytics on mass spectrometer is easily scalable a fast.

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