Cooperative Adenomyosis Network

Informed Consent Form

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Research Title：Cooperative Adenomyosis Network
Research Leader：Aijun Sun
Contact Telephone：010-69155638
RESEARCH Institution：Peking Union Medical College Hospital, Chinese Academy of Medicine Sciences.

1. RESEARCH BACKGROUND AND PURPOSES

Adenomyosis(AM) refers to a common disorder in which endometrial glands and stroma are present within the uterine musculature (uterine adenomyomatosis)，which can be present diffusely throughout the myometrium, or confined to a discrete area. The etiology of AM is still unknown. Progressive aggravated painful menstruation，menorrhagia, prolonged menstrual bleeding and infertility are the major symptoms of AM. Approximately one-third of women are asymptomatic, which is just a pathological finding after total hysterectomy due to other diseases. The malignant transformation of AM is rare but does exist. Though AM was first reported as early as 1860, and afflicting millions of women, a full understanding of the epidemiology of the disease is rather limited. The treatment for adenomyosis includes pharmacotherapy, conservative surgery and total hysterectomy, which is commonly controversial. Above all, due to the delayed childbearing age and the two-child policy in recent years, AM related infertility is increasingly severe. The lack of Expert Consensus and Clinical Guidelines about AM, especially for those who have the desire of fertility, makes it urgent for us to formulate norms and procedures in clinical practice.

Consequently, the major objectives of our research is to set up a Cooperative Network by enrolling patients of AM from multiple centers. Based on the Network platform, we try to explore several issues blow:1) Semeiology and epidemiology; 2) Diagnostic criteria (pathology, transvaginal ultrasonography or magnetic resonance image); 3) The therapeutic efficacy of Medical treatment; surgery and the fertility outcomes;3) The results of operative treatment and fertility outcomes. In addiction，we expect to conduct research on:1) The etiology of AM and endometriosis; 2)The perspective investigation of the malignant transformation of AM;3) The high-risk factors of AM;4)Writing Expert Consensus and Clinical Guidelines about AM. Finally wo hope to propel the formation of Expert Consensus and Clinical Guidelines about AM which suitable to chinese conditions, and further to standardize clinical diagnosis and treatment, improve medical quality, guarantee medical safety, and control medical cost.

2. RESEARCH CONTENTS, METHOD AND PROCESS.

It is a Prospective Multicenter Observational Cohort Study.Build up database basing on the Network platform. Licensed research centers recruite patients according to the consistent universal diagnostic criteria. 30-month follow-up will be done for every patient, trying to analyze the problems below ：1） The diagnostic strategies for AM;2) Selection of therapeutic scheme;3) Etiology of AM and endometriosis;4)The study of histology、molecular and genetics about AM and endometrial receptivity. The Follow-up visits is standardized, and the contents include : 1) The therapeutic efficacy, complication and side-effect of different treatments;2)The fertility outcomes of different reproductive choices;3) AM &menopausal symptoms and hormone therapy ; 4) Relevant issues among malignant transformation of AM.

3. POSSIBLE RISKS (OR DISCOMFORT, INCONVENIENCE)

It is an observational study. There is no additional assistant examination or treatment intervention, no additional risks to patients' health. Researchers do not charge any fee to any patients.

4. RELEVANT DETAILS CONSULTING

You have the right to consult on relevant informations. If you want to know more details about your rights and possible risks, the consulting telephone (Ethnic Committee of Peking Union Medical College Hospital) is (010)69155817.

5. RIGHT TO WITHDRAW FROM THE STUDY

You have the right to withdraw at any time from the study and to request that all previous data collected be deleted.

6. PRIVACY POLICY

Researchers will protect your privacy.

7. STATEMENT

Taking part in this study is completely voluntary. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

I understand the information printed on this form. My questions so far have been answered. I agree to take part in this study.

Signature（Subject） _____ **Date** _____

Signature（Researcher） _____ **Date** _____