

# Risk factors of Asherman's syndrome

<b>Submission date</b> 26/02/2021	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 15/03/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 02/03/2021	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Asherman's syndrome is a condition that occurs when scar tissue forms inside the uterus and/or the cervix (the opening to the uterus) following surgery to the uterus. This scar tissue (adhesions) can cause the walls of the uterus to stick together and can reduce the size of the uterus. Asherman's syndrome can affect patterns of menstruation and fertility.

The aim of this study is to compare the cells of the lining of the uterus between patients with Asherman's syndrome and patients who have undergone surgery to the uterus and have not developed Asherman's syndrome.

### Who can participate?

Patients with Asherman's syndrome and an equal number of patients a history of intrauterine surgery but without the formation of intrauterine adhesions.

### What does the study involve?

Participants will undergo a standard hysteroscopy examination (an investigation using a camera on a thin tube that is inserted into the vagina to examine the cervix and inside of the uterus) during which an endometrial biopsy will be collected for analysis. Participants will be contacted for information about their reproductive outcomes for the following two years.

### What are the possible benefits and risks of participating?

There are no special benefits or risks for patients in the study.

### Where is the study run from?

The Department of Obstetrics and Gynecology of General Faculty Hospital (Czech Republic) and 1st Medical Faculty of Charles University in Prague (Czech Republic)

### When is the study starting and how long is it expected to run for?

From January 2021 to December 2023

### Who is funding the study?

Ministry of Health (Czech Republic)

Who is the main contact?  
Dr Barbora Boudova  
barbora.boudova@vfn.cz

## Contact information

### Type(s)

Public

### Contact name

Dr Barbora Boudová

### ORCID ID

<http://orcid.org/0000-0003-0444-7160>

### Contact details

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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

Clinical, reproductive, and immunological aspects of patients with Asherman's syndrome

### Acronym

CRIAPAS

### Study objectives

Patients undergoing surgical intrauterine procedures differ according to their inflammatory reactivity, cellular response, and clinical or anamnestic parameters in the incidence of intrauterine adhesion formation.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 22/08/2019, Ethics Committee of General Faculty Hospital in Prague (Na Bojišti 1, Prague 2, 12808, Czech Republic; +420 224964131; eticka.komise@vfn.cz), ref: 1443/19 S-IV Grant

**Study design**

Single-centre observational cohort study

**Primary study design**

Observational

**Secondary study design**

Cohort study

**Study setting(s)**

Hospital

**Study type(s)**

Screening

**Participant information sheet**

Not available in web format. Available in paper form in Czech language.

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

Asherman's syndrome

**Interventions**

After enrolment, a detailed medical history will be taken and during the indicated hysteroscopy, an endometrial biopsy will be collected for single-cell analysis. Standard medical care follows. Every 6 months patients will receive a questionnaire about reproduction for another 3 years. There is no special observation (only one endometrial biopsy), and then there is 3 years follow-up.

**Intervention Type**

Other

**Primary outcome measure**

Characteristics of endometrial reactivity to insult measured using single-cell analysis during the indicated hysteroscopy at baseline

**Secondary outcome measures**

Reproductive outcomes of patients with Asherman's syndrome measured using questionnaires at baseline, 6, 12, 18, 24, 30, and 36 months

**Overall study start date**

01/06/2019

**Completion date**

30/06/2025

## Eligibility

**Key inclusion criteria**

Clinical suspicion of Asherman's syndrome verified by hysteroscopy or previous intrauterine procedure with follow-up hysteroscopy without intrauterine adhesions

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Female

**Target number of participants**

20 patients with Asherman's syndrome and 20 controls

**Key exclusion criteria**

1. Other uterine pathology (e.g. submucosal leiomyoma, adenomyosis, and cervical lesion)
2. Hormonal therapy <1 month prior to the hysteroscopy
3. Gynecological malignancy in last 12 months

**Date of first enrolment**

01/01/2021

**Date of final enrolment**

30/06/2022

## Locations

**Countries of recruitment**

Czech Republic

**Study participating centre****General Faculty Hospital**

Department of Gynecology and Obstetrics

Apolinářská 18

Prague

Czech Republic

12808

## Sponsor information

**Organisation**

General University Hospital in Prague

**Sponsor details**

U Nemocnice 2

Prague

Czech Republic

12808

+420 224961111

barbora.boudova@vfn.cz

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.vfn.cz/>

**ROR**

<https://ror.org/04yg23125>

**Funder(s)****Funder type**

Hospital/treatment centre

**Funder Name**

Všeobecná Fakultní Nemocnice v Praze

**Alternative Name(s)**

General University Hospital in Prague, VFN

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Other non-profit organizations

**Location**

Czech Republic

**Funder Name**

Ministerstvo Zdravotnictví České Republiky

**Alternative Name(s)**

Ministry of Health of the Czech Republic, MZCR

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

Czech Republic

## **Results and Publications**

**Publication and dissemination plan**

Planned publication in a impact peer-review journal and in local medical journals, PhD thesis, and presentation at medical conferences.

**Intention to publish date**

31/12/2024

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are/will be available upon request from Barbora Boudová (Barbora.boudova@vfn.cz) this will include medical history and reproductive outcomes. The results of single-cell analysis will be (already under study number, not under the name) will be shared with Biocev examining lab. Informed consent from all patients must be contained for storing the data.

**IPD sharing plan summary**

Available on request