

Risk factors of Asherman's syndrome

Submission date 26/02/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 15/03/2021	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 02/03/2021	Condition category 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

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Contact details

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

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

Study type(s)

Screening

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

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

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