ISRCTN14987772 https://doi.org/10.1186/ISRCTN14987772

Risk factors of Asherman's syndrome

Submission date	Recruitment status	[_] Prospectively registered
26/02/2021	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
15/03/2021	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
02/03/2021	Urological and Genital Diseases	[_] 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
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Contact information

Type(s)
Public

Contact name
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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
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Czech Republic
12808
+420 224961111
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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 Ceské 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