

# Comparing two antiadhesive agents for the prevention of relapse of Asherman's syndrome

<b>Submission date</b> 28/01/2022	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 05/02/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 22/05/2024	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Asherman's syndrome is a rare condition where scar tissue, also called adhesions or intrauterine adhesions (IUAs), builds up inside the uterus (womb). The main aim of this study is to compare two antiadhesive agents in the prevention of secondary developed IUAs after hysteroscopic treatment in women with Asherman's syndrome.

### Who can participate?

Women aged 18-45 years with Asherman's syndrome who are seeking treatment and future pregnancy

### What does the study involve?

The participants will follow the standard protocol of treatment - hysteroscopic resection (surgery) of IUAs will be performed with the addition of an antiadhesive barrier inside the uterine cavity at the end of the procedure, either 4DryField or Hyalobarrier gel. At 1 month after the procedure a second hysteroscopy will follow to evaluate the antiadhesive effect of the agents. Annual check-ups will be scheduled.

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

The participants will receive the antiadhesive agent free of charge as a benefit of study participation. The researchers do not anticipate any extra risks for participants because both medical preparations have excellent safety profiles and are well tolerated.

### Where is the study run from?

General Faculty Hospital and 1st Medical Faculty of Charles University (Czech Republic)

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

November 2021 to January 2023

### Who is funding the study?

Charles University (Czech Republic)

Who is the main contact?

Dr Zdenka Lisa  
zdenka.lisa@vfn.cz

## Contact information

### Type(s)

Public

### Contact name

Dr Zdenka Lisa

### ORCID ID

<https://orcid.org/0000-0003-4961-7063>

### Contact details

Apolinarska 18  
Prague  
Czech Republic  
12808  
+42 (0)224967003  
zdenka.lisa@vfn.cz

## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

01012022

## Study information

### Scientific Title

4Synless – 4DryField vs Hyalobarrier gel as antiadhesive agents used in secondary prevention of Asherman's syndrome

### Acronym

4Synless

### Study objectives

The primary objective of this study is to evaluate and compare the antiadhesive effect of 4DryField vs commonly used Hyalobarrier gel in the secondary prevention of intrauterine adhesions (IUAs) in patients with Asherman's syndrome.

The secondary goal is to determine and compare reproductive outcomes in these two groups of patients.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 30/11/2021, Ethics Committee of the General University Hospital, Prague (Na Bojisti 1, 128 00 Prague 2, Czech Republic; +42 (0)224964131; eticka.komise@vfn.cz), ref: 119/21 S-IV

### **Study design**

Single-center interventional single-blinded randomized controlled trial

### **Primary study design**

Interventional

### **Study type(s)**

Prevention

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

Prevention of secondary development of intrauterine adhesions in patients after hysteroscopic treatment of Asherman's syndrome

### **Interventions**

Patients eligible for the trial will be divided into two groups (group A = study group, group B = control group) with a 1:1 allocation ratio by pulling the letter A or B out of the envelope. Patients from group A will be given 4DryField antiadhesive agent which will be applied into the uterine cavity after the hysteroscopic resection of intrauterine adhesions (IUAs). Hyalobarrier gel will be used as an antiadhesive agent in patients in group B identically. Second-look hysteroscopy will be performed in all study patients 1 month after the primary procedure to evaluate the antiadhesive effect of the agents (4DryField vs. Hyalobarrier gel).

### **Intervention Type**

Other

### **Primary outcome(s)**

The overall assessment of the uterine cavity during the second-look hysteroscopy (1 month after the primary hysteroscopic adhesiolysis) will be done by three skilled surgeons participating in the trial. The presence and severity of de-novo adhesions will be measured using the American Fertility Society score of intrauterine adhesions at that point.

### **Key secondary outcome(s)**

Reproductive outcomes of all study patients will be recorded (annual check-ups) and evaluated for 2-5 years. The following reproductive parameters will be observed: pregnancy rate, abortion rate, live-birth rate, pregnancy complication rate, time to conception, mode of conception.

### **Completion date**

31/01/2023

## **Eligibility**

**Key inclusion criteria**

1. Women aged 18-45 years
2. Seeking pregnancy in the future
3. Confirmed Asherman's syndrome by hysteroscopy
4. Consent to their participation in the trial

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Upper age limit**

45 years

**Sex**

Female

**Total final enrolment**

23

**Key exclusion criteria**

1. Do not wish to participate in the study
2. Women out of the age range from 18 to 45 years
3. Do not meet the diagnostic criteria of Asherman's syndrome
4. Known hypersensitivity to the components of Hyalobarrier gel or 4DryField
5. Inability to perform a sufficient surgical treatment during the initial hysteroscopy

**Date of first enrolment**

01/02/2022

**Date of final enrolment**

31/08/2022

**Locations****Countries of recruitment**

Czech Republic

**Study participating centre**

Charles University

Department of Obstetrics and Gynecology

General Faculty Hospital and 1st Medical Faculty  
Apolinarska 18  
Prague 2  
Czech Republic  
12800

## Sponsor information

### Organisation

Charles University

### ROR

<https://ror.org/024d6js02>

## Funder(s)

### Funder type

University/education

### Funder Name

Univerzita Karlova v Praze

### Alternative Name(s)

Charles University, Charles University in Prague, Univerzita Karlova, Karls-Universität zu Prag, UK

### Funding Body Type

Government organisation

### Funding Body Subtype

Universities (academic only)

### Location

Czech Republic

## Results and Publications

### Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date

### IPD sharing plan summary

Data sharing statement to be made available at a later date

**Study outputs**

Output type

[Results article](#)

Details

Date created

21/05/2024

Date added

22/05/2024

Peer reviewed?

Yes

Patient-facing?

No