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

Submission date
28/01/2022

Recruitment status
No longer recruiting

Registration date
05/02/2022

Overall study status
Completed

Last Edited
22/05/2024

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
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Contact information

Type(s)
Public

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Additional identifiers

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

Primary study design
Interventional

Study design
Single-center interventional single-blinded randomized controlled trial

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 applicated 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	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		21/05/2024	22/05/2024	Yes	No