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How does hyalobarrier gel influence ovulation and pregnancy outcomes in women with scarring around the tubes and ovaries?

Submission date
27/07/2016

Recruitment status
No longer recruiting

Registration date
14/09/2016

Overall study status
Completed

Last Edited
05/12/2016

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
An adhesion is a type of scar tissue that can make the tissues or organs inside the body stick together. This type of scarring is often caused by undergoing a laproscopy (a type of operation in which the surgeon accesses the inside of the abdomen (tummy) or pelvis through a small cut. If the adhesions are around the fallopian tubes and ovaries, it can reduce fertility, as it can interfere with the monthly release of an egg necessary for conception. The removal of scarring using an anti-scarring gel is potentially useful for stopping scars from reforming after surgery. But it is not known if the gel will influence ovulation (egg production) monthly. The aim of this study is to find out whether using an anti-scarring gel called Hyalobarrier after a laproscopy has an effect on the function of ovaries.

Who can participate?
Women aged between 18 and 28 who are undergoing a laproscopy for the treatment of a condition relating to the female reproductive system, who have possible

What does the study involve?
Participants are randomly allocated to one of two groups. Both groups undergo a laproscopy according to standard procedure, but those in the first group have 10ml hyalobarrier applied around the operative site. Participants have levels of reproductive hormones measured at the start of the study and then again after three and six months, as well as undergoing ultrasound scanning at the same times to monitor their egg production.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved for participants taking part in this study.

Where is the study run from?
Princess Anne Hospital, Southampton (UK)

When is the study starting and how long is it expected to run for?
November 2011 to November 2014

Who is funding the study?
Nordic Pharma Ltd. (UK)

Who is the main contact?
Professor Ying Cheong
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
11/H0504/6

Study information

Scientific Title
Randomsied controlled trial of hyalobarrier versus no hyalobarrier on the ovulatory status of women with peri-ovarian adhesions: a pilot study

Study objectives

The aim of this study is to compare the ovarian function of women who have peri-ovarian adhesiolysis with and without Hyalobarrier as an anti-adhesion barrier.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Central Hampshire A Ethics Committee, 13/01/2011, ref: 11/H0504/6

Study design
Randomised controlled pilot study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Adnexal adhesions

Interventions
Participants are randomised to one of two groups using a computer generated random numbers table and opaque envelopes.

Intervention group: Participants receive hyalobarrier get at laparoscopy. This involves having 10ml hyalobarrier applied around the operative site was applied as per manufacturer's instruction.
Control group: Participants receive no hyalobarrier gel at laparoscopy.

Follow up for all participants involves hormonal profiling (Day 2/3 FSH and LH, and Day 21 progesterone) plus follicular tracking using ultrasonography at month 3 and month 6 post operatively.

Intervention Type
Procedure/Surgery

Primary outcome measure

Ovulatory status is measured using serum hormonal status (Day 2 FSH, LH and Day 21 progesterone) prior to the surgery and at 3 and 6 months after the surgery. Post-operatively, the participant will also undergo a follicular tracking cycle at 3 and 6 months.

Secondary outcome measures
Clinical pregnancy is measured by the presence of a fetal heart at 5-6 weeks gestation.

Overall study start date
01/11/2011

Completion date
01/11/2014

Eligibility

Key inclusion criteria
1. Aged between 18-38
2. Women were undergoing operative laparoscopy for gynaecological pathology, with possible peri-ovarian adhesions

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
38 Years

Sex
Female

Target number of participants
30

Key exclusion criteria
1. Presence of malignancies or a history of malignancies
2. Women on medications that affected ovulation
3. Women with known conditions that resulted in anovulation (PCOS, Pituitary causes)

Date of first enrolment
01/02/2012

Date of final enrolment
01/02/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Princess Anne Hospital
Coxford Road
Southampton
United Kingdom
So16 5YA

Sponsor information

Organisation
Princess Anne Hospital Southampton

Sponsor details
Coxford Road
SO16 5YA
England
United Kingdom
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02yjksy18

Funder(s)

Funder type
Industry

Funder Name
Nordic Pharma Ltd.

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal within 3 years from the trial completion date.

Intention to publish date
01/11/2017

Individual participant data (IPD) sharing plan

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	results	01/01/2017		Yes	No