Probabilistic diagnosis for the assessment of tubal pathology in subfertile women

Published: 30-06-2008 Last updated: 09-05-2024

The primary objective of the study is to evaluate whether a probabilistic diagnostic approach can replace an approach where the indication for testing for tubal pathology is made with measurement of CAT.

| Ethical review | Not approved |
|-----------------------|----------------------------------|
| Status | Will not start |
| Health condition type | Reproductive tract disorders NEC |
| Study type | Interventional |

Summary

ID

NL-OMON30849

Source ToetsingOnline

Brief title PROTUS-study

Condition

• Reproductive tract disorders NEC

Synonym tubal disease, tubal pathologie

Research involving Human

Sponsors and support

Primary sponsor: Máxima Medisch Centrum Source(s) of monetary or material Support: ZonMw projectnummer: VIDI 91.46.364

Intervention

Keyword: chlamydia antibody titer, diagnosis, tubal pathology

Outcome measures

Primary outcome

As the study aims to assess whether it is efficient to delay the

hydrolaparoscopy in low risk patients with 6 months, the primary outcome in the

number of ongoing pregnancies that occurs in 6 months. We hypothesize that this

number will not be decreased in the group of women in whom laparoscopy is

delayed.

Secondary outcome

Secondary outcomes are the number of (hydro)laparoscopies, number of patients

in whom the diagnosis tubal pathology has been made, number of patients in whom

the diagnosis tubal pathology has been delayed, and costs.

Study description

Background summary

Transvaginal hydrolaparoscopy and diagnostic laparoscopy are tests that are frequently applied in subfertile patients. They can either diagnose or rule out the diagnosis tubal pathology with 100% certainty. A disadvantage of these tests is that they are invasive, and sometimes painful, and that they carry a small risk of complications, such as bowel perforation, bleeding or infection. In view of these side effects, it is important to perform laparoscopy only in patients with a high risk on tubal pathology. The probability of tubal pathology can either be estimated with measurement of the Chlamydia Antibody Titer (CAT) or the medical history.

Study objective

The primary objective of the study is to evaluate whether a probabilistic diagnostic approach can replace an approach where the indication for testing

for tubal pathology is made with measurement of CAT.

Study design

Randomised controlled trial with randomisation of patients with discordant test results, embedded in a larger cohort study.

Intervention

Couples in whom a probability of tubal pathology based on the medical history is different from the probability based on CAT, will be randomised for immediate hydrolaparoscopy or a delay in hydrolaparoscopy of 6 months.

Study burden and risks

Participants have no additional risk as compared to regular care, as the study compares two forms of regular care.

Contacts

Public Máxima Medisch Centrum

De Run 4600 5500 MB Veldhoven Nederland **Scientific** Máxima Medisch Centrum

De Run 4600 5500 MB Veldhoven Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age Adults (18-64 years) Elderly (65 years and older)

Inclusion criteria

Subfertility > 12 months;Probability of spontaneous pregnancy > 30%;Discordant result of medical history and Chlamydia Antibody Titer

Exclusion criteria

Azospermia, knwon tubal pathology

Study design

Design

| Study phase: | 3 |
|---------------------|-----------------------------|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| | |

Primary purpose: Diagnostic

Recruitment

| NL | |
|---------------------|----------------|
| Recruitment status: | Will not start |
| Enrollment: | 800 |
| Туре: | Anticipated |

Ethics review

Not approved

| Date: | 30-06-2008 |
|--------------------|---|
| Application type: | First submission |
| Review commission: | METC Maxima Medisch Centrum (Veldhoven) |

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register CCMO

ID NL19423.015.07