Cost-effectiveness of a screening strategy for Q fever among pregnant women in risk areas: a clustered randomized controlled trial.

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To assess the effects of a screening policy for Q fever in pregnant women from areas with large numbers of Q fever cases on the pregnancy outcome and cost-effectiveness from a societal and health care perspective.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Pregnancy, labour, delivery and postpartum conditions
Study type	Interventional

Summary

ID

NL-OMON35084

Source
ToetsingOnline

Brief title
A screening strategy for Q fever among pregnant women

Condition

- Pregnancy, labour, delivery and postpartum conditions

Synonym
Q fever

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Cost-effectiveness, Pregnancy, Q fever, Screening

Outcome measures

Primary outcome

The primary endpoint is the presence of any obstetric or maternal complication after the first trimester of pregnancy, i.e. spontaneous abortion, intrauterine fetal death, termination of pregnancy, oligohydramnios, premature delivery or intrauterine growth retardation.

Secondary outcome

Secondary objectives are to describe the course of infection in pregnant women, the accuracy of the diagnostic tests used for screening, the extent to which the placenta has been infected and the costs associated with health care consumption and loss of income.

Study description

Background summary

Q fever in the Netherlands is becoming more common. A Q fever infection is a serious threat to certain risk groups, including pregnant women. Pregnant women are more often than the general population asymptomatic. Studies from France show that an infection with Coxiella burnetii may cause obstetric complications including spontaneous abortion, intrauterine fetal death, intrauterine growth retardation and oligohydramnios. The aim of this study is to assess the effectiveness and cost effectiveness of a multidisciplinary screening program, whereby pregnant women in first line healthcare in high-risk areas for Q-fever are screened with a single bloodsample during pregnancy. If found positive for Q fever, advise for antibiotic treatment will follow as part of regular healthcare. Threatment is therefor not part of the studyprotocol. The results of this study will give more insights in the risks of asymptomatic Q fever in

pregnancy and the benefits and harms of a screening strategy during pregnancy. This study will be used to give an evidence based advice to the Dutch minister of health on screening for Q fever in pregnancy.

Study objective

To assess the effects of a screening policy for Q fever in pregnant women from areas with large numbers of Q fever cases on the pregnancy outcome and cost-effectiveness from a societal and health care perspective.

Study design

We will conduct a clustered randomized controlled trial among pregnant women within an area of high transmission. The study participants will be recruited by the midwives in high risk areas, defined by postal code from the RIVM. To inform the public in this area about the study we will publish an article in local newspapers. The midwife centers will be randomized to recruit pregnant women for either the control group or the intervention group. The pregnant women will receive study information by mail using the midwives patients file. It is estimated that approximately 10,000 eligible women live in the areas of transmission. After written informed consent, they will start with the strategy for which the midwife center is randomized.

Participants will be asked for a blood sample in their second trimester of pregnancy, possibly combined with the routine structural ultrasound around 20 weeks of pregnancy to minimize hospital visit. If participants are enrolled in their third trimester, they will have their blood sampling as soon as possible after inclusion.

When taking part in the intervention group the sample will be tested immediately for Q fever. If found positive for acute or chronic Q fever, patients have to be referred, according to local protocol, to a hospital for further pregnancy monitoring and long-term bacteriostatic treatment. Follow-up blood samples are required at 14 days, 3, 6 and 12 months after the first blood sampling as part of the standardized control of Q fever disease to diagnose possible chronicity of infection. Furthermore, current routine for pregnant women being treated with antibiotics against Q fever is to perform monthly blood analyses to monitore treatment, and if the serological parameters descend, these controls are brought back to once every two months. According to local protocol patients with Q fever have to deliver in hospital. After pregnancy serology should be continued with check-ups at 3, 6 and 12 months following the current protocol. Furthermore, after delivery a bacteriocide treatment with doxycycline or an alternative will be started by the specialist as part of regular health care.

In the control arm the blood samples will be stored, and analyzed for Q fever

after delivery. If tested positive for Q fever after pregnancy antibiotics could be started if needed as part of regular health care.

At baseline, a questionnaire will be administered to all participants asking about the current pregnancy , pregnancy outcome of any previous pregnancies and demographics. Further risk factors for pregnancy outcome will also be obtained such as smoking and drinking behavior, risk-elevating comorbities and medication use.
After delivery all relevant outcome data will be collected by questionnaires filled out by the midwife, GP or specialist after delivery, notably the presence of obstetric complications. One month after delivery or end of pregnancy, a last questionnaire will be administered to the participant to verify potential long-term consequences of Q fever, potential loss of income, health-related quality-of-life, fatigue and depressive symptoms. Furthermore questions will be asked about the condition of the newborn and risk-accessing questions for Q fever infection will be asked.

In the context of the secondary research questions an extra blood sample will be required, and placentas as well as amniotic fluid will be collected after delivery from both the intervention and the control group. The latter will only take place in a limited number of women and only if they gave birth in a hospital.

All participants will receive usual care and will be asked to visit the general practitioner if symptoms of Q fever occur. He/she will start diagnostic research and treatment or will refer the patient to the hospital. Furthermore, both arms have access to an expert team for support.

Intervention

The intervention is screening for Q fever with a single bloodsample during pregnancy. Treatment of Q fever positive patients is part of standard care of the specialist, so is not part of the intervention in this study.

Study burden and risks

There is no risk associated with blood drawing other than the occasional standard discomfort associated with venapuncture, i.e. hematoma, redness, swelling, pain or fainting and thus the burden is minimal.
Information of risks and adverse effects of antibiotic treatment will be given to the pregnant womem by the prescribing physician, since this treatment is part of standard health care. Antibiotic treatment is not part of this studyprotocol.

The advantage might be that pregnant women in this area, if recruited by a midwife center which is randomised for the intervention group, have the

possibility to be screened for Q fever, and if found positive that they can be treated for it. However, this study will show us if this is a true advantage or not, especially for asymptomatic women. Also, an expert team will be available for possible questions for both groups.

The participants need to consent that any information that is observed which may have clinical relevance will be given to the researcher. This study will give better insights into the effects of a screening strategy for Q fever on pregnancy outcome and cost-effectiveness.

The study will primarily provide insights into the balance of risks of undetected and detected q-fever during pregnancy.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Subjects have to fulfil the following criteria:
- being pregnant under first line healthcare
- being eighteen years or older
- having signed an informed consent form
- having a estimated date of delivery between June 1th 2010 en December 31th 2010

Exclusion criteria

The exclusion criteria are:
- unable to fulfill study procedures
- absence of informed consent
- have been tested positive for Q fever prior to pregnancy
- unable to understand Dutch

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-04-2010
Enrollment:	4000
Type:	Actual

Ethics review

Approved WMO Date:	10-03-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	09-07-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	ID
CCMO	NL30340.042.09