Methotrexate versus Expectant management in women with ectopic pregnancy.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25989

Source
NTR

Brief title
METEX study

Health condition

ectopic pregnancy
Pregnancy of unknown location (PUL)
low and plateauing serum hCG
methotrexate
expectant management

Sponsors and support

Primary sponsor: Academic Medical Center, University of Amsterdam
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Source(s) of monetary or material Support: ZonMW Clinical Fellow Grant

Intervention

Outcome measures

Primary outcome

The primary outcome measure is an uneventful decline of serum hCG to an undetectable level by primary treatment, i.e. single dose systemic methotrexate or expectant management.

Secondary outcome

Secondary outcomes are number of (re)interventions (additional methotrexate injections or surgical procedures for persistent trophoblast and/or clinical signs), treatment complications, future fertility, health related quality of life, financial costs, and patients preferences.

Study description

Background summary

The incidence of ectopic pregnancy is approximately 1-2 % of all pregnancies. An early diagnosis is possible by transvaginal sonography in combination with serum human chorionic gonadotrophin (hCG) measurements. Women with low but plateauing serum hCG concentrations have thus far been offered medical treatment with methotrexate. Systemtic methotrexate has been shown to be effective treatment for tubal pregnancy compared with surgery in several randomised trials. Methotrexate was cost effective in women with serum hCG < 2.000 IU/L but had a more negative impact on patients health related quality of life. Side effects include stomatitis, conjunctivitis, gastritis-enteritis, impaired liver function, bone marrow depression, and photosensitivity. Methotrexate has been shown to be safe with virtually no adverse effects reported on reproductive outcome. However, there is no evidence on the effects of treatment in this particular subgroup of women with low but plateauing serum hCG concentrations, which represents about 10% of women presenting with suspected ectopic pregnancy. Expectant management has been practiced based on the acknowledgement that the natural course of many early ectopic pregnancies is a self limiting process, ultimately resulting in tubal abortion or reabsorption. The objective is whether in women with suspected ectopic pregnancy with low but plateauing serum hCG concentrations additional treatment with systemic methotrexate in a single dose intramuscular regimen is superior over expectant management in terms of tubal rupture, future pregnancy, health related quality of life and costs.

Study objective

To study whether in women with suspected ectopic pregnancy with low but plateauing serum

hCG concentrations additional treatment with systemic methotrexate in a single dose intramuscular regimen is superior over expectant management in terms of tubal rupture, future pregnancy, health related quality of life and costs.

Intervention

Systemic methotrexate in a single dose intramuscular regimen (1 mg/kg body weight) versus expectant management.

Contacts

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Eligibility criteria

Inclusion criteria

All hemodynamically stable patients
> 18 years with either a suspected ectopic pregnancy (a visible ectopic pregnancy or an ectopic mass on Trans Vaginal Sonography) and a plateauing serum hCG concentration < 1,500 IU/L or with a Pregnancy of Unknown Location (PUL) and a plateauing serum hCG concentration < 2,000 IU/L (persisting PUL).

Exclusion criteria

Patients with a viable ectopic pregnancy, signs of tubal rupture or active intra abdominal bleeding, abnormalities in liver or renal function or in full blood count.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2006
Enrollment:	72
Type:	Actual

Ethics review

Positive opinion

Date:	19-02-2006
Application type:	First submission

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
NTR-new	NL555
NTR-old	NTR611
Other	: N/A
ISRCTN	ISRCTN48210491

Study results

Summary results
N/A