Methotrexate versus Expectant management in women with ectopic pregnancy.

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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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25989

Bron
NTR

Verkorte titel
METEX study

Aandoening

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

Ondersteuning

Primaire sponsor: Academic Medical Center, University of Amsterdam
Obstetrics and Gynaecology (H4-205)
Meibergdreef 9
1105 AZ AMSTERDAM
THE NETHERLANDS
tel: +31 20 5663693

fax: +31 20 6963489
Overige ondersteuning: ZonMW Clinical Fellow Grant

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

Academic Medical Center, (AMC), Department of Obstetrics and Gynaecology, H4-205,
P.O. Box 22660
P.J. Hajenius
Meibergdreef 9

Amsterdam 1100 DD
The Netherlands
+31 (0)20 5663693 or +31 (0)20 5663654

Wetenschappelijk

Academic Medical Center, (AMC), Department of Obstetrics and Gynaecology, H4-205,
P.O. Box 22660
P.J. Hajenius
Meibergdreef 9

Amsterdam 1100 DD
The Netherlands
+31 (0)20 5663693 or +31 (0)20 5663654

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-06-2006
Aantal proefpersonen:	72
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	19-02-2006
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL555
NTR-old	NTR611
Ander register	: N/A
ISRCTN	ISRCTN48210491

Resultaten

Samenvatting resultaten
N/A