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Methotrexate versus expectant management in women with ectopic pregnancy

Submission date 28/04/2006	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/04/2006	**Overall study status** Completed	
Last Edited 23/05/2016	**Condition category** Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.metexstudy.nl/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2006-003003-39

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Methotrexate versus expectant management in women with ectopic pregnancy

Acronym
METEX

Study objectives
To study whether in women with suspected ectopic pregnancy with low but plateauing serum human Chorionic Gonadotropin (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.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Medical ethical committee (METC) of the Academic Medical Centre, Amsterdam, ref: 06/075
2. Central Committee on Research involving Human Subjects (CCMO), ref: NL11168.018.06, EudraCT number: 2006-003003-39

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Patient information can be found on the trial website at http://www.metexstudy.nl/ (Dutch only)

Health condition(s) or problem(s) studied
Ectopic pregnancy

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

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Methotrexate

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

Secondary outcome measures
1. Number of (re)interventions (additional methotrexate injections or surgical procedures for persistent trophoblast and/or clinical signs)
2. Treatment complications
3. Future fertility
4. Health related quality of life
5. Financial costs
6. Patients preferences

Overall study start date
01/06/2006

Completion date
01/06/2009

Eligibility

Key inclusion criteria
1. All haemodynamically stable patients
2. greater than 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 less than 1500 IU/l or with a Pregnancy of Unknown Location (PUL) and a plateauing serum hCG concentration less than 2000 IU/l (persisting PUL)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants

Key exclusion criteria
1. Patients with a viable ectopic pregnancy
2. Signs of tubal rupture or active intra-abdominal bleeding
3. Abnormalities in liver or renal function or in full blood count

Date of first enrolment
01/06/2006

Date of final enrolment
01/06/2009

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Center (AMC)
Amsterdam
Netherlands
1100 DD

Sponsor information

Organisation
Academic Medical Center (AMC) (The Netherlands)

Sponsor details
Department of Obstetrics and Gynaecology
P.O. Box 22660
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Sponsor type
University/education

Website
http://www.amc.uva.nl/index.cfm?sid=1

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Research organisation

Funder Name
ZonMw

Alternative Name(s)
Netherlands Organisation for Health Research and Development

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Netherlands

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	19/06/2008		Yes	No
Results article	results	01/01/2013		Yes	No
Abstract results	results (abstract)	01/06/2013		No	No
Results article	health-related quality of life results	01/09/2015		Yes	No