

Methotrexate versus expectant management in women with ectopic pregnancy

Submission date 28/04/2006	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input checked="" type="checkbox"/> Protocol
Registration date 28/04/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 23/05/2016	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2006-003003-39

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

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)

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

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?
Results article	results	01/01/2013		Yes	No
Results article	health-related quality of life results	01/09/2015		Yes	No
Protocol article	protocol	19/06/2008		Yes	No
Abstract results	results (abstract)	01/06/2013		No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes