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A single-centre randomised controlled trial of Antibiotic Prophylaxis before second-trimester Genetic Amniocentesis in women: the APGA trial

Submission date 23/10/2007	**Recruitment status** No longer recruiting
Registration date 30/10/2007	**Overall study status** Completed
Last Edited 10/06/2021	**Condition category** Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PROT-PRSV-98/0012

Study information

Scientific Title
A single-centre randomised controlled trial of Antibiotic Prophylaxis before second-trimester Genetic Amniocentesis in women: the APGA trial

Acronym
APGA Trial

Study objectives
We hypothesise that:
1. There exists a risk factor for infection that could be responsible for rupture of the membranes (preterm Premature Rupture Of Membranes [pPROM]) and often for foetal death, and that this risk factor is present even before the amniocentesis procedure is undertaken
2. Antibiotic prophylaxis before amniocentesis can prevent pPROM and/or foetal death

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval obtained from the Local Ethics Committee of the "Artemisia Medical Institute Network" (created according to the guidelines reported in the "Decreto Ministeriale (DM) 15/7 /1997", Ministry of Health of Italy) on the 12th September 1998.

Study design
Prospective, randomised controlled single-centre study on prophylactic therapy strategy

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Preterm Premature Rupture Of Membranes (pPROM), foetal death

Interventions
Intervention:
Oral azithromycin 500 mg daily for the three days prior to the amniocentesis procedure, in three doses taken at 24-hour intervals.

Control:
No therapy.

Both groups have a scan on the day of the amniocentesis. The women have to be discharged 30 minutes after completion of the procedure. The patients that present any complications, within 4 weeks, must to be checked into the Centre with a scan and PROM test. The coordinators, after 4 weeks, will check by phone that all women will not come back to the centre for prescribed control. All study personnel were blinded to treatment assignment for the duration of the study.

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome measure
To determine the efficacy of antibiotic prophylaxis in second-trimester amniocentesis in preventing the foetal death in both groups, assessed four weeks after the procedure.

Secondary outcome measures
1. To determine the incidence of pPROM in both groups, defined as a rupture of the membranes, assessed four weeks after the procedure
2. To evaluate the incidence of foetal death after the pPROM in both groups, assessed four weeks after the procedure

Overall study start date
02/01/1999

Completion date
20/12/2005

Eligibility

Key inclusion criteria
1. Pregnant women aged greater than or equal to 18 years
2. All women requested a second trimester genetic amniocentesis with the same chosen operator

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
30000

Total final enrolment
34923

Key exclusion criteria
1. Non-viable foetus (also found after the randomisation)
2. Major foetal abnormalities (also found after the randomisation)
3. Leakage of amniotic fluid
4. Bleeding in the past week
5. Fever
6. Use of any antibiotics within the past 14 days or of long-acting injectable penicillin
7. Known allergy to the specific antibiotic used

Date of first enrolment
02/01/1999

Date of final enrolment
20/12/2005

Locations

Countries of recruitment
Italy

Study participating centre
Viale Liegi 49
Rome
Italy
00198

Sponsor information

Organisation
CERMET (Certification and Research for Quality) and Total Quality Management (Italy)

Sponsor details
Via Velletri 10
Rome
Italy
00198

Sponsor type
Industry

Website
http://www.cermet.it/

Funder(s)

Funder type
Research organisation

Funder Name
Italian Society of Prenatal Diagnosis and Feto-Maternal Medicine (Italy)

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?
Results article		01/06/2009	10/06/2021	Yes	No