

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	☐ Prospectively registered
Registration date 30/10/2007	Overall study status Completed	☐ Protocol
Last Edited 10/06/2021	Condition category Pregnancy and Childbirth	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

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)

Funder(s)

Funder type

Research organisation

Funder Name

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

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		01/06/2009	10/06/2021	Yes	No