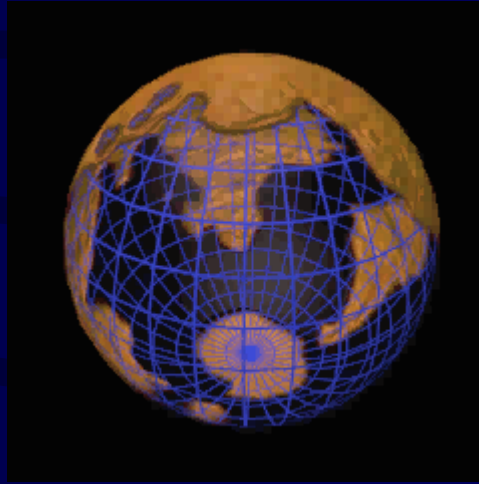


# Re-entry Grant Project



***Prevalence of cervical and vaginal infections in pregnant women***

**Dr Juan C. Vazquez**

# Objective

- To know the prevalence of cervical and vaginal infections of Chlamydia trachomatis, Mycoplasma hominis, Ureaplasma urealyticum and beta-haemolytic Group B Streptococcus in pregnant women

# Description

- Observational (cross-sectional) study in 600 pregnant women coming to “America Arias” Hospital, City of Havana, Cuba, for routine ultrasound, at gestational age between 20-26 weeks, and living in municipalities near the Hospital.

# Laboratory Procedures

- Four laboratory samples will be taken . One from the cervix , to know the prevalence of Chlamydia trachomatis, and three from the upper part of the vagina, to know the prevalence of Mycoplasma hominis, Ureaplasma urealyticum and beta-haemolyticum Group B Streptococcus

# Forms

- Consent
- Inclusion
- Treatment
- Final Outcomes

# Inclusion Criteria

- Gestational age between 20-26 weeks
- Agree to participate

# Exclusion Criteria

- Gestational age: less than 20 or more than 26 weeks
- Do not agree to participate
- Previous adverse reaction to macrolides
- Multiple pregnancy
- Suspected or confirmed foetal malformation (US study)
- Liver disease or hepatotoxic drugs

# Discontinuation Criteria

- Requested by patient
- PROM or delivery
- Lost to follow-up



# Treatment

- Patients testing positive for *Chlamydia trachomatis* infection will take a single dose of azithromycin (1 g orally), as well as their partners. The treatment will be ambulatory.

# Data Management and Analysis

- Data will be coded, monitored and verified by means of Data Base and EPI-INFO System programs
- Analysis will be performed by means of frequency tables, using means and standard deviations

# Timetable

*The study will last two years:*

- Staff training: 2 months
- Preparation of antibiotics: 2 months
- Recruitment: 12 months
- Data collection: 16 months
- Data analysis: 4 months
- Staff meetings (1, 12, 24 months)
- Interim reports (12 and 18 months)
- Final analysis and final report

# Anticipated problems

- Allocation of the patients testing positive for *Chlamydia trachomatis* to give them and their partners the treatment

# Solution

- Co-ordination with primary care clinics to allocate patients, and visits of the Principal Investigator and collaborating personnel

# Material resources

- Laboratory equipment
- Antibiotics
- Office supplies
- Supplies for personnel computers
- Forms printing
- Transportation
- Communications

# Human Resources

- Principal Investigator
- Collaborating personnel
- Secretary
- Statistician