# Study of proliferation in the mammary epithelium of young women using combined oral contraceptives

Submission date Recruitment status Prospectively registered 11/11/2006 No longer recruiting [ ] Protocol Statistical analysis plan Registration date Overall study status 14/12/2006 Completed [X] Results [ ] Individual participant data Last Edited Condition category 01/10/2008 Cancer

#### Plain English summary of protocol

Not provided at time of registration

#### Contact information

#### Type(s)

Scientific

#### Contact name

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## Additional identifiers

**EudraCT/CTIS** number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 685/000

# Study information

#### Scientific Title

#### **Acronym**

EPEMAHO (Estudo da Proliferacao no Epitelio da Mama de usuarias de Anticoncepcional Hormonal Oral)

#### Study objectives

Combined Oral Contraceptives (COC) affect the proliferation rate of mammary epithelium in young women (below 36 years of age) to a greater degree than older women.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

This study, at the time of registration, received appropriate ethics committee approval from the Health Ministry of Brazil and the National Committee of Research Ethics on December 12, 2000.

#### 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

#### Health condition(s) or problem(s) studied

Fibroadenoma

#### **Interventions**

Goal:

To determine the impact of one cycle of a combined oral contraceptive on breast homeostasis, we evaluated the Proliferation Index (PI), determined by the expression of KI-67, in normal human mammary epithelial cells and correlated it with cellular proliferation in spontaneous menstrual cycles during the same period.

#### Methods:

Normal breast tissue samples were obtained from 82 patients who were randomised in two groups:

Group A - Forty two women received one cycle of a Combined Oral Contraceptive (COC) (30  $\mu$ g ethinyl estradiol and 150  $\mu$ g levonorgestrel) administrated daily for 21 days, beginning on the first day of the menstrual cycle.

Group B - Forty patients experienced a natural menstrual cycle. No placebo was given. Excision of the fibroadenoma then took place.

Menstrual cycle phase characterisation was based on the date of the last period and subsequent menses, and on progesterone serum levels obtained just before the time of biopsy.

#### Intervention Type

Drug

#### Phase

**Not Specified** 

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

Ethinyl estradiol and levonorgestrel

#### Primary outcome measure

Successful excision of fibroadenoma; the histologically normal tissue (at least 1 cm away from the FA) was studied in women with COC and with natural cycles during the first, second, third and fourth week of the menstrual cycle.

#### Secondary outcome measures

Not provided at time of registration

#### Overall study start date

23/11/2000

#### Completion date

15/12/2004

# Eligibility

#### Key inclusion criteria

- 1. Females between 14 to 36 years of age
- 2. Undergoing excision of Fibroadenomas (FA) (a condition thought not to be associated with an increase risk of cancer) at the Department of Gynecology, Mastology Division: Benign mammary diseases, Federal University of São Paulo, Paulista Medical School
- 3. Signed an informed consent before enrolment in the study
- 4. Regular menstrual cycles (intervals of  $28 \pm two days$ ) in the previous six months
- 5. A known date of the last menstrual period

#### Participant type(s)

**Patient** 

#### Age group

Adult

Sex

#### Female

#### Target number of participants

82 patients

#### Key exclusion criteria

- 1. Use of hormone therapy in the previous 12 months
- 2. Pregnancy
- 3. Breast feeding during the previous 12 months
- 4. Any endocrine disorder
- 5. Taking any medication at the time that tissue for the study was obtained

#### Date of first enrolment

23/11/2000

#### Date of final enrolment

15/12/2004

### Locations

#### Countries of recruitment

Brazil

#### Study participating centre Rua Jose Maria Lisboa

Sao Paulo Brazil 01423000

# Sponsor information

#### Organisation

Federal university of Sao Paulo (Universidade Federal de Sao Paulo) (Brazil)

#### Sponsor details

Escola Paulista de Medicina Rua Botucatu 740 - Vila Clementino Sao Paulo Brazil 01454-010 +55 (11) 570 3321 dgnarvaiza@intertim.com.br

#### Sponsor type

University/education

#### Website

http://www.unifesp.br/

#### **ROR**

https://ror.org/02k5swt12

# Funder(s)

#### Funder type

University/education

#### Funder Name

Federal University of Sao Paulo and Health Ministry of Brazil (Brazil)

#### **Funder Name**

The National Commission of Ethics in Research (Comissao Nacional de Etica em Pesquisas [CONEP]) (Brazil) (registration number: 685/000)

## **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	results	01/09/2008		Yes	No