ISRCTN59588862 https://doi.org/10.1186/ISRCTN59588862

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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Maria Alicia Navarrete

Contact details
Rua Jose Maria Lisboa
1036 apto 111
Sao Paulo
Brazil
01423000
+55 (11) 3088 0096
chile@stanford.edu

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 µg ethinyl estradiol and 150 µg 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 ± 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