ISRCTN46864306 https://doi.org/10.1186/ISRCTN46864306

# Impact of pharmaceutical intervention in women with epilepsy

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 27/04/2010 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 07/06/2010 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 21/02/2022 | Nervous System Diseases | |

**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**
01-2010

# Study information

### Scientific Title
Impact of pharmaceutical intervention in the treatment and quality of life of women with epilepsy: a randomised controlled pragmatic clinical trial

### Acronym
IPHIWWE

### Study objectives
Will the intervention of the pharmacist in the therapy of women with epilepsy to optimise treatment and improve their quality of life?

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Local medical ethics committee (Fundación Liga Central Contra la Epilepsia, sede Bogotá, LICCE, Acta 18/2009 Comité de Ética), 11/08/2009, ref: CEI-A1. Acta 18 de 2009

### Study design
Randomised controlled pragmatic trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Other

### Study type(s)
Quality of life

### Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

### Interventions
This is a two-armed pragmatic trial. The intervention group will receive usual medical care and are additionally given pharmaceutical care, health education and therapeutic drugs monitoring for six months. The control group continued with standard medical care.

All the patients continued drug treatment prescribed by the physician. Questionnaire measures will be administered to all participants at the beginning of baseline recording and at the end of the study.

### Intervention Type
Other

### Phase
Not Applicable

### Primary outcome measure
Quality of Life in Epilepsy Inventory-31 (QOLIE-31). Questionnaire measures will be administered to all participants at the beginning of baseline recording and at the end of treatment (six months).

### Secondary outcome measures
Questionnaire measures will be administered to all participants at the beginning of baseline recording and at the end of treatment (six months):
1. Liverpool Adverse Events Profile
2. Spanish Center for Epidemiologic Studies, Depression Scale
3. Drug related problems

### Overall study start date
03/05/2010

### Completion date
28/02/2011

## Eligibility

### Key inclusion criteria
1. Female, over 18 years
2. Diagnosis of epilepsy for more than a year
3. In treatment with antiepileptic drugs
4. Having at least one crisis in the last year
5. Ability to comply with the directions of the study

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Female

### Target number of participants
182 patients

### Total final enrolment
182

### Key exclusion criteria
1. Active major psychiatric disorder
2. Physical deficit (e.g., hemiplegia) or mental (e.g., mental retardation), preventing them from answering questionnaires
3. Drug/alcohol dependence
4. Involvement, earlier in the pharmaceutical care program of the institution

### Date of first enrolment
03/05/2010

### Date of final enrolment
28/02/2011

## Locations

### Countries of recruitment
Colombia

### Study participating centre
**Crr 30 45-03 Edificio 450**
Bogotá
Colombia
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## Sponsor information

### Organisation
Universidad Nacional de Colombia (Colombia)

### Sponsor details
Dirección de Investigación Sede Bogotá
Cra. 45 26-85 (Edificio "Uriel Gutiérrez") Of. 206 y 219
Bogotá
Colombia
001

### Sponsor type
University/education

### Website
http://www.unal.edu.co/

### ROR
https://ror.org/059yx9a68

# Funder(s)

### Funder type
University/education

### Funder Name
Universidad Nacional de Colombia (Colombia) - Research Division of Bogotá (DIB) (ref: 202010011419 Quipu Code)

# Results and Publications

### Publication and dissemination plan
Not provided at time of registration

### Intention to publish date

### Individual participant data (IPD) sharing plan
Not provided at time of registration

### 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 | 31/10/2014 | | Yes | No |
| Results article | | 15/02/2022 | 21/02/2022 | Yes | No |