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

Impact of pharmaceutical intervention in women with epilepsy

Submission date
27/04/2010

Recruitment status
No longer recruiting

Registration date
07/06/2010

Overall study status
Completed

Last Edited
21/02/2022

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised controlled pragmatic trial

Study type(s)
Quality of life

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(s)
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).

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Female

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
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001

Sponsor information

Organisation
Universidad Nacional de Colombia (Colombia)

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

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