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A randomised controlled trial to compare the cost-effectiveness of tricyclic antidepressants, selective serotonin re-uptake inhibitors and lofepramine

Submission date
25/04/2003

Recruitment status
No longer recruiting

Registration date
25/04/2003

Overall study status
Completed

Last Edited
08/11/2022

Condition category
Mental and Behavioural Disorders

[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 96/61/11

Study information

Scientific Title
A randomised controlled trial to compare the cost-effectiveness of tricyclic antidepressants, selective serotonin re-uptake inhibitors and lofepramine

Acronym
AHEAD

Study objectives
This project will be a three-arm randomised controlled open label controlled study of the cost effectiveness of tricyclic antidepressants, SSRIs and lofepramine in the primary care setting. Outcome will be assessed over a one year period using well established clinical, quality of life, and economic measures at intervals of one or three months. The objectives are 1) to compare the cost effectiveness and cost utility of the initial choice of SSRIs and tricyclic antidepressants in general practice and 2) to compare the cost effectiveness and cost utility of the initial choice of SSRIs and lofepramine in general practice.

Please note that, as of 10 January 2008, the anticipated end date of this trial has been updated from 31 July 2002 to 31 July 2003.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration.

Study design
Three-arm randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Mental and behavioural disorders: Depression, anxiety, neuroses

Interventions
Tricyclic antidepressants, selective serotonin re-uptake inhibitors and lofepramine

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
tricyclic antidepressants, SSRIs and lofepramine

Primary outcome measure
Quality of life and economic measures.
Clinical outcomes are being assessed through use of the Clinical Interview Schedule, Rviesed version; the Hospital Anxiety and Depression Scale; the Euroqol; and the SF-36 Quality of Life Scale. Use of health services is being assessed through patient-completed questionnaires, and through detailed examination of general practice medical records.

Secondary outcome measures
Not provided at time of registration.

Overall study start date
01/02/1999

Completion date
31/07/2003

Eligibility

Key inclusion criteria
The sample group is of 327 patients who are prescribed antidepressant drugs by their general practitioner. The sociodemographic characteristics and other features of this group will be analysed, to evaluate whether the sample is representative of the wider population of general practice patients received antidepressant treatment.

Participant type(s)
Patient

Age group
Not Specified

Sex
Both

Target number of participants
327

Key exclusion criteria
Not provided at time of registration.

Date of first enrolment
01/02/1999

Date of final enrolment
31/07/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Academic Psychiatry
Southampton
United Kingdom
SO14 0YG

Sponsor information

Organisation
Department of Health (UK)

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Quarry House
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Sponsor type
Government

Website
http://www.dh.gov.uk/en/index.htm

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK)

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	HTA monograph	01/05/2005		Yes	No