ISRCTN39857520 https://doi.org/10.1186/ISRCTN39857520

A pilot randomised controlled trial of antidepressant medication switching for treatment-refractory depression in primary care

Submission date
15/10/2004

Recruitment status
No longer recruiting

Registration date
13/01/2005

Overall study status
Completed

Last Edited
28/10/2016

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Paul Walters

Contact details
MRC Fellow
Section of Primary Care Mental Health
Institute of Psychiatry
Denmark Hill
London
United Kingdom
SE5 8AF
-
p.walters@iop.kcl.ac.uk

Additional identifiers

Protocol serial number
PALBFWA

Study information

Scientific Title
A pilot randomised controlled trial of antidepressant medication switching for treatment-refractory depression in primary care

Acronym
SWITCH

Study objectives
The main hypothesis to be tested is:
In depressed primary care patients who have failed to recover after treatment with one antidepressant for at least four weeks and at a standard dose, switching their antidepressant medication to one from a different antidepressant class and continuing it for a further four weeks will be more effective than continuing the initial antidepressant for a further four weeks at the same dose.

Secondary hypotheses to be explored are:
1. That there is a positive association between social adversity, the number of life events and the response to antidepressant medications.
2. That non-compliance adversely effects the outcome independently of social adversity and life events
3. That both patient and doctors views of depression and antidepressant medication are associated with response to antidepressant medication

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Depression, Treatment-resistant

Interventions
1. Antidepressant medication switched (intervention):
Patients randomised to the intervention arm will have an appointment booked with their GP within 48 hours of the baseline assessment. At this appointment the GP will follow pre-determined guidelines for switching the Selective Serotonin Reuptake Inhibitor (SSRI) to an alternative antidepressant from a different antidepressant class. The Maudsley Prescribing Guidelines (6th Edition) will be used to guide General Practitioners (GPs) switching antidepressants (incorporating the recommended wash-out periods between antidepressant medications). Patients will continue on the second antidepressant for four weeks at a standard dose.

For patients unable to tolerate the second antidepressant due to side effects, GPs will follow guidelines to prescribe an alternative antidepressant so that each patient will have a full trial of four weeks on a second antidepressant from a different antidepressant class. The GP will be asked to assess the patient at two and four weeks (following best-practice guidelines) but can see the patient more often as deemed necessary and refer for counselling as necessary.

2. Same antidepressant medication continued (control):
Patients randomised to the control arm will have an appointment booked with their GP within 48 hours of the baseline assessment. Patients randomised to the control group will be asked by their GP to continue on the initial SSRI for a further four weeks. The GP will be asked to assess the patient at two and four weeks (following best-practice guidelines) but can see the patient more often as deemed necessary and refer for counselling as necessary.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
To determine the feasibility of conducting a larger randomised controlled trial to examine clinical effectiveness of switching an antidepressant medication to another from a different antidepressant class in primary care patients with treatment-refractory depression.

Key secondary outcome(s))
1. Whether demographic variables, social adversity, life events, physical health and disability, are associated with outcome
2. Whether patient and doctor beliefs about depression and antidepressant medication are associated with outcome

Completion date
30/09/2006

Eligibility

Key inclusion criteria
Consenting patients aged 16 years or over with a score of 13 or more on the Hamilton Rating Scale for Depression (HAM-D), 9 or more on the Beck Depression Inventory and who have been compliant with a specific serotonin reuptake inhibitor at a standard dose for at least four weeks (as ascertained by self report questionnaire) will be invited to participate in the study.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Temporary registrations
2. Under 16 years
3. Currently receiving psychological therapies (cognitive behavioural therapy, problem solving therapy, interpersonal therapy)
4. Other psychotropic medications apart from benzodiazepines
5. Case note diagnosis of schizophrenia or bipolar affective disorder
6. Currently being treated for drug or alcohol dependence
7. Suicidal patients
8. Psychotic depression as evidenced by delusions and/or hallucinations
9. Patient treated by secondary psychiatric services
10. Non-English speaking

Date of first enrolment
01/02/2005

Date of final enrolment
30/09/2006

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
MRC Fellow
London
United Kingdom
SE5 8AF

Sponsor information

Organisation
King's College London (UK)

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Research council

Funder Name
MRC Clinical research training fellowship

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration