

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	<input checked="" type="checkbox"/> Prospectively registered
Registration date 13/01/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 28/10/2016	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

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

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 affects 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

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

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 measure

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.

Secondary outcome measures

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

Overall study start date

01/02/2005

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

Age group

Adult

Sex

Both

Target number of participants

100

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**

England

United Kingdom

Study participating centre

MRC Fellow
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Sponsor information

Organisation
King's College London (UK)

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Sponsor type
University/education

ROR
<https://ror.org/0220mzb33>

Funder(s)

Funder type
Research council

Funder Name
MRC Clinical research training fellowship

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