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GENetic and clinical Predictors Of treatment response in Depression

Submission date
17/09/2003

Recruitment status
No longer recruiting

Registration date
19/09/2003

Overall study status
Completed

Last Edited
27/09/2011

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] 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
G0200243

Study information

Scientific Title

Acronym
GENPOD

Study objectives
We wish to identify genetic and clinical predictors of response to SSRIs and NaRIs in depressive illness. Hypotheses:
1. Those who are homozygous for the insertion allele polymorphism in the promoter region of the 5HT transporter who are allocated SSRIs will have an improved response compared to those on NaRIs. This also implies that those who are not homozygous will have reduced response on SSRIs compared to those on NaRIs.
2. Those who have more severe depressive disorders who are allocated NaRIs and less severe disorder allocated SSRIs will have a better response compared to the other two groups

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)
Not Specified

Health condition(s) or problem(s) studied
Mental and Behavioural Disorders

Interventions
1. Reboxetine 4mg bd
2. Paroxetine 20mg

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Reboxetine, Paroxetine

Primary outcome(s)
Beck depression inventory total score (BDI) at 6 weeks adjusted for baseline BDI score.

Key secondary outcome(s))
Not provided at time of registration

Completion date
22/05/2008

Eligibility

Key inclusion criteria
18-74 years with the more severe depressions in whom the GP and patient have already agreed that antidepressants should be prescribed. We will therefore only include those with a Clinical Interview Schedule - Revised (CIS-R) score of ≥20, a Beck Depression Inventory (BDI) score of ≥15 and a diagnosis of International Statistical Classification of Diseases and Related Health Problems, tenth revision (ICD-10) depressive episode F32 and F33 (from CIS-R).

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
74 years

Sex
Not Specified

Key exclusion criteria
Pregnant and breast feeding women, patients with psychotic illness, alchohol or substance abuse problems, patients with medical contraindications to Citalopram or Reboxetine. (June 2006: Exclusion criteria were provided as follows: Potential subjects who have taken antidepressant medication within 2 weeks, who cannot complete self-administered scales, who have a psychosis or major substance or alcohol abuse. The GP will exclude anyone who has medical contraindications or in whom participation in the trial is not appropriate.)

Date of first enrolment
23/02/2004

Date of final enrolment
22/05/2008

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Division of Psychiatry
Bristol
United Kingdom
BS6 6JL

Sponsor information

Organisation
Medical Research Council (UK)

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (G0200243) (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

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	01/06/2011		Yes	No
Protocol article	protocol	22/05/2008		Yes	No