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GENetic and clinical Predictors Of treatment response in Depression

Submission date	Recruitment status	[X] Prospectively registered
17/09/2003	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/09/2003	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
27/09/2011	Mental and Behavioural Disorders	

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
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

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 measure
Beck depression inventory total score (BDI) at 6 weeks adjusted for baseline BDI score.

Secondary outcome measures
Not provided at time of registration

Overall study start date
23/02/2004

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
74 Years

Sex
Not Specified

Target number of participants
887 Added 18/08/09: recruitment ongoing

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
England

United Kingdom

Study participating centre
Division of Psychiatry
Bristol
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Sponsor information

Organisation
Medical Research Council (UK)

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Sponsor type
Government

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, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	22/05/2008		Yes	No
Results article	results	01/06/2011		Yes	No