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REmission MEchanisms in Depression

Submission date	Recruitment status	[ ] Prospectively registered
29/04/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
29/04/2010	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
26/11/2019	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

Protocol serial number
4357

Study information

Scientific Title
REmission MEchanisms in Depression

Acronym
REMEDi

Study objectives

We will recruit 48 unmedicated depressed participants aged 18 - 55 years with a Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM-IV) major depressive episode and 24 age and sex matched controls. Depressed participants will be scanned using magnetic resonance imaging, before and after administration of 8 weeks treatment with daily citalopram (20 mg, increasing to 40 mg at week 4 if necessary). Half of the controls will be retested after 8 weeks but receive no treatment. Also, prior to oral administration of citalopram, depressed participants will be randomised to receive citalopram or saline infusion in the scanning protocol. Depressed participants will be treated by the clinical research fellow and monitored for treatment response, side effects and suicidal risk by face-to-face appointments at 2, 4, 6 and 8 weeks and by phone interviews at 1, 3 and 5 weeks.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Stockport LREC approved on the 3rd December 2007

Study design
Randomised interventional treatment trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Mental Health Research Network, Primary Care Research Network for England; Subtopic: Depression, Not Assigned; Disease: Depression, All Diseases

Interventions
8 week treatment with citalopram 20 - 40 mg, citalopram pharmacoMRI. Patients are randomised to citalopram infusion (7.5 mg) versus saline during fMRI scanning at baseline in a 3:1 ratio.

Follow up length: 2 months
Study entry: registration only

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Citalopram

Primary outcome(s)
Baseline neuronal responses predicting outcome a 8 weeks

Key secondary outcome(s))

1. Montgomery Asberg Depression Rating Scale (MADRS), measured at baseline and 8 weeks
2. Neuronal responses to emotional processing tasks using fMRI, measured at baseline and 8 weeks depressed patients versus controls

Completion date
31/05/2010

Eligibility

Key inclusion criteria
Depressed subjects:
1. DSM-IV major depressive episode with a Montgomery Asberg Depression Rating Scale (MADRS) score greater than 20
2. Psychotropic drug-free for greater than 2 weeks (2 months for fluoxetine)

Controls:
3. Psychiatrically well

All:
4. Good physical health
5. Aged 18 - 55 years, either sex

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Depressed subjects:
1. Duration of depressive episode greater than 1 year or depression superimposed on dysthymia
2. Failure to respond to 2 antidepressants given for 6 weeks at an adequate dose in current episode
3. Failure to respond to citalopram or escitalopram in current episode
4. Allergy or intolerance to citalopram or escitalopram
5. Contraindications to selective serotonin reuptake inhibitor (SSRI) treatment (e.g., history of peptic ulcer/gasterointestinal [GI] bleeding or taking non-steroidal anti-inflammatory drugs [NSAIDs], in the absence of concurrent ulcer-protective treatment)
6. Other concurrent psychotropic medication except for small stable doses of short acting hypnotics
7. Electroconvulsive therapy (ECT) or lithium in current episode

8. Significant suicidal risk or likely need for other psychiatric intervention during the study period
9. Other current co-morbid Axis I psychiatric disorders except anxiety disorders (excluding OCD) secondary to depression
10. Primary cluster A or B Axis II (personality) disorder
11. History of psychotic, bipolar or organic psychiatric disorder

Controls:
12. Personal psychiatric history including Axis II (personality) disorder
13. Significant family psychiatric history (eg psychosis, recurrent affective disorder)
14. Psychotropic medication

All:
15. Medical condition that might compromise subject safety or interfere with interpretation of results
16. History of significant head trauma (loss of consciousness greater than 5 minutes)
17. Current medication for a medical condition that would compromise subject safety or interfere with interpretation of results in the judgement of the investigator (e.g., possible exceptions intermittent analgesics, contraceptive pill, occasional inhaler for mild asthma)
18. Subjects whose English is insufficiently good to enable them to validly complete the questionnaires or perform simple computer-based tasks
19. Pregnancy or no effective contraception in women of childbearing age
20. Any illicit drug use in the last 2 months and a lifetime history of a DSM-IV substance or alcohol misuse disorder
21. Current Alcohol use above 14 units/week for women and 21 units/week for men
22. Excessive caffeine use (greater than 6 cups of coffee/day)
23. Smoking greater than 10 cigarettes/day
24. Contraindications to scanning (determined by standard screening instrument)
25. Likely not to be able to complete the full study for any reason

Date of first enrolment
01/04/2008

Date of final enrolment
31/05/2010

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Neuroscience and Psychiatry Unit
Manchester
United Kingdom
M13 9PT

Sponsor information

Organisation
University of Manchester (UK)

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (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

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available upon request from Prof. Emeritus Ian M Anderson (ian.anderson@manchester.ac.uk) in an anonymised form and in keeping with MRC data sharing guidance.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2012	26/11/2019	Yes	No
Results article	results	15/03/2019	26/11/2019	Yes	No

Results article	results	01/09/2009	26/11/2019	Yes	No
Results article	results	01/12/2013	26/11/2019	Yes	No
Results article	results	01/09/2009	26/11/2019	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes