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Assessment of Augmentation Strategies to Optimize the Therapeutic Response to Mirtazapine in Major Depression

Submission date
13/09/2005

Recruitment status
No longer recruiting

Registration date
15/02/2006

Overall study status
Completed

Last Edited
16/08/2011

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Study objectives
1. A six-week treatment with a daily dose 20 mg of fluoxetine by itself will produce a clinically significant antidepressant response
2. A six-week treatment with mirtazapine in combination with any of the following three antidepressant medications: fluoxetine, bupropion, or venlafaxine, by producing a sustained increase in 5-hydroxytryptamine (5-HT) synaptic availability in the presence of epinephrine (NE) reuptake blockade or increased NE release, will induce a more robust clinical response compared to those patients receiving only fluoxetine
3. A six-week treatment with a combination of mirtazapine and venlafaxine or with mirtazapine and bupropion, by producing initially a greater synaptic availability of NE than with mirtazapine alone, and by enhancing 5-HT neurotransmission rapidly as well, will induce a more rapid clinical response. Therefore, patients receiving a six-week treatment with these two combinations of antidepressant medications will demonstrate an earlier onset of their clinical response compared to those receiving only fluoxetine or fluoxetine plus mirtazapine.

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
Major depression

Interventions
This is a double-blind study comparing the effects of fluoxetine alone to those of mirtazapine plus fluoxetine, mirtazapine plus venlafaxine, and mirtazapine plus bupropion in patients presenting with major depression. At the end of the six-week trial, remitters that received either

fluoxetine plus placebo or fluoxetine plus mirtazapine will be maintained on fluoxetine alone for six months and those that received either bupropion or venlafaxine will be maintained on mirtazapine alone for the same period of prolongation. Non-responders will be offered alternate treatment strategies by the principal investigator.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
1. Mirtazapine 2. Fluoxetine 3. Bupropion 4. Venlafaxine

Primary outcome measure
The primary efficacy variables are the total Hamilton Depression Rating Scale (HAM-D), total Montgomery-Asberg Depression Rating Scale (MADRS), Clinical Global Impression (CGI) improvement scale, CGI severity scale, the percentage of responders (i.e. improvement of 50% or more on the total MADRS), and the percentage of remitters (i.e. a score of 8 or less on the HAM-D)

Secondary outcome measures
The secondary variable is the depression subscale of the Symptom Checklist-90-R (SCL-90-R)

Overall study start date
01/07/2001

Completion date
31/12/2005

Eligibility

Key inclusion criteria
1. Male or female patients between 18 and 65 years of age
2. Diagnosis of major depression according to the Diagnostic and Statistical Manual of Mental Disorders - fourth edition (DSM-IV) (American Psychiatric Association, 1994) using the Structural Clinical Interview for DSM-IV (SCID) (Spitzer and Williams, 1988)
3. Initial global score 18 on the first 17 items of the 24-item Hamilton Depression Rating Scale
4. Written informed consent signed by the patient

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex

Both

Target number of participants
100

Key exclusion criteria
1. Patients who have not participated in another clinical trial in the past 30 days
2. Evidence of suicidal tendencies
3. Evidence of significant physical illness contraindicating the use of fluoxetine, mirtazapine, venlafaxine or bupropion, found on physical or in the laboratory data obtained during the first week of the study
4. Mental retardation (Intelligence Quotient [IQ] lower than 80) rendering the response to investigators unreliable
5. Pregnancy, or absence of adequate contraceptive method in women with childbearing potential
6. Concurrent use of psychotropic medication such as neuroleptics, mood stabilizers or regular use of high doses of benzodiazepines
7. Lack of response to fluoxetine for the present episode

Date of first enrolment
01/07/2001

Date of final enrolment
31/12/2005

Locations

Countries of recruitment
Canada

United States of America

Study participating centre
1145 Carling Avenue
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Sponsor information

Organisation
Organon International Inc. (USA)

Sponsor details

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Sponsor type
Industry

ROR
https://ror.org/02891sr49

Funder(s)

Funder type
Industry

Funder Name
Organon International Inc (USA)

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?
Results article	results	01/03/2010		Yes	No