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Evaluating the safety and efficacy of PM011 as an antidepressant for patients with mild to moderate depression

Submission date	Recruitment status	[ ] Prospectively registered
19/04/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
29/04/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
09/08/2013	Mental and Behavioural Disorders	[ ] 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

CCRG_06_01

Study information

Scientific Title
A randomized, double-blind, placebo-controlled trial to evaluate the safety and efficacy of PM011 as an antidepressant

Study objectives
The optimal dose of PM011 would decrease 17-item HAM-D score more than placebo control.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. The institutional review board (IRB) of the Catholic University of Korea, Seoul St Mary's hospital approved on the 19/02/2008 (ref: KCMC07MS274)
2. The IRB of East-West Neo Medical Centre approved on the 30/11/2007 (ref: KHNMC-OH-IRB 2007-013)
3. The IRB of Wonkwang University Sanbon Oriental Medical Centre approved on the 30/11/2007 (ref: WONSBHB IRB 2008-3)
4. The IRB of Sanji University Oriental Medical Centre approved (ref: SJ2008-050101)
5. The Catholic University of Korea, St. Vincent's hospital approved on the 21/09/2009 (ref: VC09MDMS0043)

Study design
Randomised double blind parallel group multi-dose placebo controlled phase IIb trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Mild to moderate depression

Interventions
Patients are randomised to receive
1. PM011 (extract of nelumbinis semen [lotus seed]), low dose 1200mg/day (400mg pill x 3 times daily)
2. PM011, moderate dose 2400 mg/day (800 mg pill x 3 times daily)

3. PM011, high dose 4800 mg/day (1600 mg pill x 3 times daily)
4. Placebo control, consisting of corn starch and milk sugar

The trial consists of screening (visit 1), run-in phase (visit 2/day -7), treatment period (visit 3/day 1, visit 4/day 15, visit 5/day 29, visit 6/day 43) and follow-up (by telephone/day 50). The run-in phase is during 1 week. In run-in phase, all participants would take placebo control.

The duration of treatment is 6 weeks. The total duration of the trial including follow-up period is 9 weeks.

Intervention Type
Drug

Phase
Phase II/III

Drug/device/biological/vaccine name(s)
PM011 (extract of nelumbinis semen [lotus seed])

Primary outcome measure
17-item Hamilton Rating Scale for Depression (HAM-D), measured at screening, run-in phase (day -7 and if more than one week since screening), days 1, 15, 29 and 43 of treatment.

Secondary outcome measures
1. Montgomery-Asberg Depression Rating Scale, measured at days 1, 15, 29 and 43
2. Clinical Global Impression (CGI), measured at days 1, 15, 29 and 43
3. Brief version of World Health Organization Quality of Life Questionnaire (WHOQOL), measured at day 1 and 43 (start and end of treatment)
4. Visual Analogue Scale (VAS), measured at days 1, 15, 29 and 43
5. International Index of erectile function; male, measured at day 1 and 43 (start and end of treatment)
6. Female Sexual Function Index (FSFI); female, measured at day 1 and 43 (start and end of treatment)
7. Symptom Checklist-90-R (SCL-90-R), measured at day 1 and 43 (start and end of treatment)

Overall study start date
09/07/2008

Completion date
31/12/2010

Eligibility

Key inclusion criteria
1. Patient aged 18 to 65 male or female
2. Patient diagnosed as major depressive disorder by DSM-W, had major depressive episode during last 30 days (before screening day)
3. 17-item Hamilton Rating Scale for Depression (HAM-D) scored 18 to 25
4. Patient given written informed consent form
5. Patient given written informed consent form of genetic study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
136 (34 for each group)

Key exclusion criteria
1. Woman who is pregnant, breast-feeding or not using appropriate contraception
2. Patient who has risk committing suicide, above 2 on the HAM-D suicide item (item #3)
3. Patient who has neurologic or psychiatric disorder except depression (schizophrenia, bipolar disorder, epilepsy, drug abuse, alcohol abuse, panic disorder or agitation that needs treatment etc)
4. Seriously irritable patient
5. Patient who has clinically significant liver disease or liver enzyme levels elevated to at least twice the upper normal limit
6. Patient who has chronic renal failure or over 1.5 folds blood creatinine level compared with the upper normal limit
7. Patient whose elevated laboratory test level that cause affective disorder (ex. thyroid disorder)
8. Patient who is not responder of anti-depressant or has history of non-response
9. Patient that had participated in another clinical trial in 1 month before screening day
10. Patient who is hypersensitive or has allergy about intervention
11. Patient who has digestive disease that could interfere with drug absorption
12. Patient who is intellectual and developmental disabled or emotionally irritable
13. Patient whose HAM-D score decreased more than 20% during placebo run-in phase
14. Patient who is taking hormone therapy or has history of hormone therapy
15. Patient who has received drug therapy or psychotherapy that meets exclusion criteria during clinical trial
16. Patient who has stressful life events or acute stress reaction (stressful life event and mental health score over 200 points at screening).

Date of first enrolment
09/07/2008

Date of final enrolment
31/12/2010

Locations

Countries of recruitment
Korea, South

Study participating centre
Center for Clinical Research and Genomics
Seoul
Korea, South
130-701

Sponsor information

Organisation
Purimed (South Korea)

Sponsor details
#203 A compartment of Chun-taeck building
Hwikyung-1-dong
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Seoul
Korea, South
130-091

Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Purimed (South Korea)

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