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Evaluation of the effect of agomelatine and escitalopram on emotions and motivation in healthy male and female volunteers

Submission date	Recruitment status	[X] Prospectively registered
24/06/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
04/08/2011	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
18/04/2018	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration and not expected to be available in the future

Contact information

Type(s)
Scientific

Contact name
Prof Guy Goodwin

Contact details
University of Oxford
Department of Psychiatry
Warneford Hospital Headington
Oxford
United Kingdom
OX3 7JX

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CL1-20098-081

Study information

Scientific Title
Evaluation of the effect of agomelatine and escitalopram on emotions and motivation in healthy male and female volunteers

Study objectives
Current study hypothesis as of 23/07/2012:
To assess the effects of agomelatine and escitalopram on emotional blinding, emotional processing and motivation during 9 weeks treatment in healthy male and female volunteers

Previous study hypothesis until 23/07/2012:
To assess the effects of agomelatine and escitalopram on emotional blinding, emotional processing and motivation during 8 weeks treatment in healthy male and female volunteers

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval was obtained before recruitment of the first participants

Study design
Randomised double-blind placebo-controlled multicentric study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Major Depressive Disorder

Interventions
1. A randomised, double-blind study with parallel group of therapeutic oral doses of agomelatine and escitalopram
2. 9 weeks treatment period and 1 week of follow-up period

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Agomelatine, escitalopram

Primary outcome measure
1. Emotional blunting will be assessed by using the Oxford Depression Questionnaire (ODQ) at week 0/ week 2/ week 8 and end of study
2. Emotional processing: Facial expression recognition task/Emotional categorisation task/the faces dot-probe task/Emotional memory free recall task/Emotional memory forced recognition task at week 1 and week 8
3. Motivation: Sensitivity to reward and punishment task/Motivation and effort duration task/ Gait speed task/Motivation score at week 0/ week 1/ week 2 and week 8

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/10/2011

Completion date
31/05/2013

Eligibility

Key inclusion criteria
1. Healthy male and female volunteers aged between 18 and 45 years (both inclusive)
2. A Body index (BMI) between 18.0 and 30.0 (both inclusive)
3. Ability and/or willingness to undergo psychological test battery, motivation test battery and self-rating questionnaires or clinician-rated questionnaires including sexual activity questionnaire
4. Speaks fluent English
5. Negative urine pregnancy test for women of childbearing potential at inclusion
6. Using consistently and correctly method of birth control such as implants, injectables, oral contraceptives, some intra-uterine device or surgical sterilization
7. Negative drug abuse and breath ethanol test

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

Key exclusion criteria
1. Any surgical procedure since the selection visit
2. Intake of any medication (except paracetamol at the dose of 1.5g/day and oral contraceptives) since the selection visit
3. Previous experience of Emotional Test Battery

Date of first enrolment
01/10/2011

Date of final enrolment
31/05/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Oxford
Oxford
United Kingdom
OX37JX

Sponsor information

Organisation
Institut de Recherches Internationales Servier (France)

Sponsor details
50 rue Carnot
Suresnes
France
92284

Sponsor type
Industry

Website
http://www.servier.com/

ROR

https://ror.org/034e7c066

Funder(s)

Funder type
Industry

Funder Name
Institut de Recherches Internationales Servier (France)

Results and Publications

Publication and dissemination plan
Publication plan:
Summary results are published in https://clinicaltrials.servier.com.

Intention to publish date

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from https://clinicaltrials.servier.com if a Marketing Authorisation has been granted after 1st January 2014.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results				No	No