

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

<b>Submission date</b> 24/06/2011	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 04/08/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 18/04/2018	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## 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?
<a href="#">Basic results</a>				No	No