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

Submission date	<b>Recruitment status</b> No longer recruiting	<ul><li>[X] Prospectively registered</li><li>Protocol</li></ul>		
24/06/2011				
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

#### Protocol serial number

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

## Study type(s)

**Treatment** 

#### 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(s)

- 1. Emotional blunting will be assessed by using the Oxford Depression Questionnaire (ODQ) at week 0/ 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

#### Key secondary outcome(s))

No secondary outcome measures

#### 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

#### Healthy volunteers allowed

No

## Age group

Adult

#### Lower age limit

18 years

#### Sex

Αll

#### 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

United Kingdom

Study participating centre
University of Oxford
Oxford
United Kingdom
OX37JX

# Sponsor information

#### Organisation

Institut de Recherches Internationales Servier (France)

#### **ROR**

https://ror.org/034e7c066

# Funder(s)

## Funder type

Industry

#### Funder Name

Institut de Recherches Internationales Servier (France)

# **Results and Publications**

# 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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes