

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

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

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Contact details

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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 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

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

All

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

England

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