

Treatment of hot flashes with low-dose risperidone

Submission date 23/06/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 08/07/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 08/07/2010	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Hung-Ming Wu

Contact details
135 Nanxiao St.
Changhua City
Changhua
Taiwan
500

Additional identifiers

Protocol serial number
KTCT-P2a

Study information

Scientific Title
Treatment of hot flashes with low-dose risperidone: An uncontrolled pilot study

Study objectives
By chance, risperidone was reported to have an effect on remission of hot flashes. We postulate that risperidone could serve as a potential drug to treat hot flashes.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Research Ethics Committee of Kuang-Tein General Hospital approved on the 20th of March 2005 (ref: KTCTP2a)

Study design

Pilot prospective non-randomised uncontrolled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Hot flashes

Interventions

Patients complete hot flash diaries regarding the frequency and severity of hot flashes everyday in a one-week baseline period, in the 3-month risperidone treatment period, and during the first two weeks after total risperidone withdrawal.

Intervention Type

Other

Phase

Phase I

Primary outcome(s)

The efficacy of risperidone for hot flashes is assessed by the average number of hot flashes per day, and the average daily hot-flash score (frequency × severity)

Key secondary outcome(s)

None

Completion date

31/05/2006

Eligibility**Key inclusion criteria**

Menopausal (perimenopausal or postmenopausal) women with at least a moderate severity (i.e., ≥ 2 on a 04 scale) of hot flashes

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

1. Menopausal women who take antipsychotic drug or/and antidepressants
2. Menopausal women who have breast cancer

Date of first enrolment

01/06/2005

Date of final enrolment

31/05/2006

Locations**Countries of recruitment**

Taiwan

Study participating centre

135 Nanxiao St.

Changhua

Taiwan

500

Sponsor information**Organisation**

Kuang-Tien General Hospital (Taiwan)

ROR

<https://ror.org/001yjfq23>

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

Kuang-Tien General Hospital (Taiwan) - investigator led study

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration