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Treatment of hot flashes with low-dose risperidone

Submission date	Recruitment status	[_] Prospectively registered
23/06/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
08/07/2010	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
08/07/2010	Urological and Genital Diseases	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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 sereve 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)

Primary study design
Interventional

Study design
Pilot prospective non-randomised uncontrolled trial

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/001yjqf23

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