ISRCTN05964399 https://doi.org/10.1186/ISRCTN05964399

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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)

Study design
Pilot prospective non-randomised uncontrolled trial

Primary study design
Interventional

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details below to request a patient information sheet

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 measure
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)

Secondary outcome measures
None

Overall study start date
01/06/2005

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

Age group
Adult

Sex
Female

Target number of participants
6

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)

Sponsor details
135 Nanxiao St.
Changhua City
Changhua
Taiwan
500

Sponsor type
Hospital/treatment centre

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration