Treatment of hot flashes with low-dose risperidone

Submission date 23/06/2010	Recruitment status No longer recruiting	 Prospectively registered Protocol
Registration date 08/07/2010	Overall study status Completed	 Statistical analysis plan Results
Last Edited 08/07/2010	Condition category Urological and Genital Diseases	 Individual participant data 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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Contact details

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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., \geq 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

Menopausal women who take antipsychotic drug or/and antidepressants
 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