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A double-blind, placebo-controlled trial of Zoloft's® Effects on Symptoms and survival Time in Advanced Cancer

Submission date 22/12/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 31/03/2005	**Overall study status** Completed	
Last Edited 10/08/2009	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.ctc.usyd.edu.au/trials/cancer/other_cancer_trials.htm

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 1.0, dated October 2004 - ACTRN012605000381684

Study information

Scientific Title

Acronym
The ZEST Trial

Study objectives
Not provided at time of registration

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Double-blind placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Advanced Cancer

Interventions
Sertraline 50 mg, one tablet once daily by mouth with or without food or identical placebo, one tablet once daily by mouth with or without food.

Intervention Type
Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)
Sertraline (Zoloft®)

Primary outcome measure
1. Quality of life (depression, anxiety and fatigue)
2. Survival
3. Adverse events

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/05/2002

Completion date
31/12/2006

Eligibility

Key inclusion criteria
1. Advanced cancer defined by the presence of metastatic disease and treatment with palliative intent, that is to improve length and quality of life, but without realistic hope of cure
2. Symptomatic score greater than or equal to 4/10 for depression, anxiety, fatigue or lack of energy at baseline (assessment tool: Patient DATA form)
3. Eastern Cooperative Oncology Group (ECOG) performance status 0-2
4. Life expectancy of >3 months
5. Serum creatinine <200 µmol/l and bilirubin <30 µmol/l within 28 days of randomization
6. Able to complete baseline quality of life instruments
7. Availability and willingness for follow-up
8. Written informed consent
9. Women of childbearing potential must be taking adequate contraceptive precautions

Participant type(s)
Patient

Age group
Not Specified

Sex
Both

Target number of participants
450

Key exclusion criteria
1. Major depression, in other words, a clear indication for antidepressant treatment
2. Delirium i.e. impaired cognitive function (as detected by the Confusion Assessment Method, a screening tool for delirium assessing onset, course, inattention, disorganised thinking, level of

consciousness)
3. History of hypersensitivity to sertraline
4. Diagnosis of carcinoid tumour
5. Coexisting conditions contraindicating treatment with serotonin reuptake inhibitors
6. Past history of schizophrenia or bipolar affective disorder
7. Treatment with antidepressants (including St John's Wort) or procarbazine within the last 4 weeks. Amitriptyline may be used at a daily dose of 25 mg or less as a co-analgesic or for urinary frequency, and is not an exclusion criterion.
8. Pregnant or lactating women. Women of childbearing potential are eligible if taking adequate contraceptive precautions.
9. Treatment with Tramadol in the last 7 days (ZEST participants should not use Tramadol because of the possibility of an interaction causing the serotonin syndrome)

Date of first enrolment
01/05/2002

Date of final enrolment
31/12/2006

Locations

Countries of recruitment
Australia

Study participating centre
NHMRC Clinical Trials Centre
Camperdown, New South Wales
Australia
1450

Sponsor information

Organisation
National Health and Medical Research Council (NHMRC) Clinical Trials Centre (Australia)

Sponsor details
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University of Sydney
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Sponsor type

Research organisation

ROR
https://ror.org/011kf5r70

Funder(s)

Funder type
Research organisation

Funder Name
New South Wales Cancer Council (Australia)

Funder Name
Pfizer - supplied study drug (sertraline and placebo) free of charge

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2007		Yes	No