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A double blind placebo controlled discontinuation of citalopram in adolescents with major depression

Submission date 05/09/2005	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 05/09/2005	**Overall study status** Stopped	
Last Edited 28/01/2019	**Condition category** Mental and Behavioural Disorders	

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
NCT00249886

Secondary identifying numbers
MCT-53732

Study information

Scientific Title
A double blind placebo controlled discontinuation of citalopram in adolescents with major depression

Study objectives
Adolescents with Major Depression who recover from an acute trial of citalopram will have a lower relapse rate over a 6 month period when continued on citalopram as compared to subjects randomly assigned to discontinue to placebo.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Sunnybrook Hospital University of Toronto Clinic, 24/09/2002

Study design
Double blind placebo controlled discontinuation

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Major Depressive Disorder

Interventions
Citalopram versus placebo

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Citalopram

Primary outcome measure

Relapse = the subject meets criteria for an episode of major depression.

Secondary outcome measures
A CGI-I score of -2 or -3 (on a 7 point scale) or more, reflecting at least 'moderate worsening' of the clinical condition.

Overall study start date
01/04/2002

Completion date
31/03/2006

Eligibility

Key inclusion criteria
1. Major depression determined from both clinical interview and the Kiddie-Sads-Present and Lifetime Version
(K-SADS-PL)
2. Subjects who score greater than 16 on the first 17 items of the 29 item Hamilton Rating Scale for Depression - Seasonal Affective Disorder (HRSD-SAD) version or those who score greater than 12 on the 17 item of the 29 items HRSD and greater than 7 on the atypical items
3. Age 13 to 18 years
4. Both sexes; females who have reached menarche and are sexually active will be advised to take adequate birth control (BCP or two barrier methods)
5. Outpatient at the time of initiation of the continuation phase
6. Ability to give informed consent

Participant type(s)
Patient

Age group
Child

Lower age limit
13 Years

Upper age limit
18 Years

Sex
Not Specified

Target number of participants
214

Key exclusion criteria
1. Past or currently hypomanic or manic episode
2. Currently meets criteria for conduct disorder
3. Current psychotic symptoms
4. Substance dependence in the last 3 months

5. Significant medical condition that would contra-indicate the use of antidepressant agents
6. Pregnancy
7. Past treatment with citalopram for major depression

Date of first enrolment
01/04/2002

Date of final enrolment
31/03/2006

Locations

Countries of recruitment
Canada

Study participating centre
2075 Bayview Av
Toronto
Canada
M4N 3M5

Sponsor information

Organisation
Sunnybrook and Women's College Health Sciences Centre (Canada)

Sponsor details
2075 Bayview Avenue
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Sponsor type
Not defined

ROR
https://ror.org/03wefcv03

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-53732)

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