

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

Submission date
05/09/2005

Recruitment status
Stopped

☐ Prospectively registered

☐ Protocol

Registration date
05/09/2005

Overall study status
Stopped

☐ Statistical analysis plan

☐ Results

Last Edited
28/01/2019

Condition category
Mental and Behavioural Disorders

☐ Individual participant data

☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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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

Toronto

Canada

M4N 3M5

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