Validation of the 'Suicidality: Treatment Occuring in Paediatrics (STOP) Suite of Measures' in Clinical and Non-clinical Child and Adolescent Populations

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Ethical review	Not approved
Status	Will not start
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON38610

Source
ToetsingOnline

Brief title
STOP study

Condition

- Other condition

Synonym
Psychiatric disorder

Health condition

Psychiatrische aandoeningen waarvoor een anti-psychoticum of anti-depressiva wordt voorgeschreven

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: EU FP7 Suicidality

Intervention

Keyword: Children and Adolescents, Medication, Treatment-related Suicide (Attempts)

Outcome measures

Primary outcome

The goal of this study is to develop a reliable and efficient screening tool for suicidal ideation and suicide risk in children and adolescents specifically addressed to capture the possible influence of medication side effects or mechanism of action. The rating scale will have one form for children and adolescents, one form to be addressed to their parents and another form to be completed by the clinician.

Secondary outcome

More specifically, the objectives are:

1. To design a rating scale for assessing suicidality in children and adolescents including developing different versions for children, parents, and clinicians

2. To translate the rating scales into all the languages of the countries collaborating in the study and to carry out a first evaluation of the psychometric properties of the resulting scales.

Study description

Background summary

There is insufficient data available safety of using many medications in children and adolescents who may have illness that itself predispose them to suicidality. There is also insufficient data available about the time-course about medication related suicidality and what happens to it over the long-term. Further, there is insufficient data available about the long-term safety, especially about medication related suicidality, especially since there is evidence to suggest that paediatric populations may represent a vulnerable group, compared to adults.

Study objective

The goal of this study is to develop a low burden, reliable and efficient screening tool for suicidal ideation and suicide risk in children and adolescents specifically addressed to capture the possible influence of medication side effects or mechanism of action.

Study design

Questionnaire Validation

Study burden and risks

The compilation of new questionnaires should not result in additional risks to the patient. Indeed an assessment of suicidality (i.e. asking the child if he/she had now or in the past, ideas or behaviors related to suicide, the circumstances and severity of damage) is always carried out in all patients when performing clinical evaluation that leads to the diagnosis.
A direct benefit to the participants may result in a more accurate assessment of suicidal symptoms, if any, that may be useful for better planning of treatment.
Indirect benefits will be to help create a scale that will be used in different types of psychopharmacological studies, allowing the collection of better data about drug-related suicidality in children.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

Children and adolescents between the ages of 8 and 18 years old, and their parents or main carer.
Children and adolescents newly treated with an antidepressant or cognitive behavior therapy for depression or antipsychotic medication for any indication (this inclusion criteria is for clinical population only).
All parents and patients have provided informed consent/assent in accordance with ethical regulations.

Exclusion criteria

If the main carer does not have a reasonable level of Dutch, they will be excluded from the study. This is because a reasonable level of Dutch is required to complete the baseline information.
Children who are deemed by the clinician to be too vulnerable to participate (for clinical population only).
The child/adolescent will be excluded if the main carer is not available to participate in the

study.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	250
Type:	Anticipated

Ethics review

Not approved

Date:	03-10-2013
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL44194.091.13