kofam

Koordinationsstelle Forschung am Menschen

CASE STUDY

Randomized trial of behavioural activation and antidepressant medication in the treatment of adolescents with major depression: a randomized trial

CATEGORISING

Kind
Research project involving living people

Type

Subtype
Clinical trial with medicinal products (including combinations according to Art. 2 Para. 1 Letters f and g MedDO)

BACKGROUND

Those diagnosed with depression are overwhelmed by sadness that lasts for at least two weeks. Other symptoms include changes in appetite or sleep patterns, lack of energy or motivation, and even thoughts of suicide. Those diagnosed with depressions often need medication, therapy, or a combination of the two to relieve their symptoms and regain their normal function. This study sought to determine if behavioural activation therapy (a psychological intervention) was as effective as antidepressant medication (fluoxetine) for adolescents diagnosed with depression.

METHODS

This study randomly allocated adolescents between 12-16 years old, who met criteria for Major Depressive Disorder, to receive behavioural activation therapy or fluoxetine (Fluoxetin-Mepha®) over the course of 18 weeks. Those randomized to fluoxetine visited their psychiatrist regularly but did not receive psychotherapy. Those who received behavioural activation therapy received between 18-20 one-hour sessions of individual therapy that focused on increasing enjoying and rewarding behaviours. The primary outcome was the difference in mean change of depressive symptoms as measured with the Children's Depression Rating Scale - Revised (CDRS-R).

QUESTIONS OF THE CATEGORISER

Does the research project come under the scope of application of the Human Research Act?
Yes

BECAUSE
This project was based on a study protocol that defines the exact procedures to be used. It included a relatively large number of persons and was not based on individual cases ("method-driven search for generalizable knowledge", defined as research by HRA). Adolescents ("persons") between 12-16 years old, who suffered from major depressive disorder ("research concerning human diseases") were treated either with behavioural therapy or fluoxetine (Fluoxetin-Mepha®).

Is the research project a project involving living persons?
Yes

BECAUSE
Adolescents ("persons") who suffered from major depressive disorder were included in this research project.

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Is the research project a clinical trial as defined by ClinO or ClinO-MD?
Yes

BECAUSE
The investigator randomly allocated ("prospectively assigned") adolescents ("persons") who suffered from major depressive disorder to receive either behavioural therapy or fluoxetine (Fluoxetin-Mepha®) ("health related intervention [therapeutic measure]") to assess the between-group difference in mean change of depressive symptoms, measured with the Children's Depression Rating Scale - Revised (CDRS-R) ("to investigate its effect on health").

Does the trial involve investigating medicinal products (including combinations according to Art. 2 Para. 1 Letters f and g Medical Device Ordinance (MedDO) from the July 1, 2020)?
Yes

BECAUSE
The effects of behavioural therapy and fluoxetine (Fluoxetin-Mepha®) were investigated (Fluoxetin-Mepha® is a "medicinal product") in this randomised-controlled trial.

Does the trial involve investigating a medical device (in vitro diagnostics excluded) or any other device as defined in Article 1 of the Medical Devices Ordinance (MedDO) (Status as of 26 May 2022)?
No

BECAUSE

Does the trial investigate an intervention that is neither a therapeutic product nor a transplant product, nor a product according to Art. 2a para. 2 Therapeutic Products Act (TPA) (Status from May 26, 2021), nor a transplant?
Yes

BECAUSE
The effects of behavioural therapy and fluoxetine (Fluoxetin-Mepha®) were investigated (Fluoxetin-Mepha® is a "medicinal product") in this randomised-controlled trial. Behavioural therapy (psychotherapy) is not a medicinal product/device, a transplant or transplant product, a gene therapy, or a pathogenic organism.

Does the trial investigate gene therapy or a pathogenic organism?
No

BECAUSE

Is the investigational medicinal product (IMP) authorised in Switzerland?
Yes

BECAUSE
The effects of behavioural therapy and fluoxetine (Fluoxetin-Mepha®) were investigated in this randomised-controlled trial. Fluoxetin-Mepha®, is "authorised" for the Swiss market (approval number Fluoxetin-Mepha®: 54049, 57235 (Swissmedic)).

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Is a placebo used in the trial, or is the original status of the medicinal product or its packaging as approved by Swissmedic modified?
No

BECAUSE
The effects of behavioural therapy and fluoxetine (Fluoxetin-Mepha®) were investigated in this randomised-controlled trial. Fluoxetin-Mepha® is "authorised" for the Swiss market and are provided "as is", unchanged except for their labels.

Does the IMP administration comply with the specifications in the summary of product characteristics (SPC)?
No

BECAUSE
The effects of behavioural therapy and 10 mg fluoxetine (Fluoxetin-Mepha®), titrated as necessary to 40 mg/day for 18 weeks, were investigated in this randomized-controlled trial that included adolescents between 12-16 years of age, who suffered from major depressive disorder. This use complies with the approved indication and dosage (depression, maximum 80 mg/day). But the use of fluoxetine for persons under 18 years is not recommended. The intended use of fluoxetine in this research project differed from the specifications in the summary of product characteristics.

Does the deviation from the specifications in the SPC concern indication or dosage?
Yes

BECAUSE
The effects of behavioural therapy and 10 mg fluoxetine (Fluoxetin-Mepha®), titrated as necessary to 40 mg/day for 18 weeks, were investigated in this randomized-controlled trial, which included adolescents between 12-16 years old, who suffered from major depressive disorder. This use complies with the approved indication and dosage (depression, maximum 80 mg/day). But the use of fluoxetine for persons under 18 years of age is not recommended. The intended use of fluoxetine in this research project differed from the specifications in the summary of product characteristics. This research project deviated from the approved specifications only in regard to the indication (treatment of depression of persons less than 18 years of age).

Does the indication lie within the same disease group in the ICD-10 classification as stated in the SPC (disease group indicated by the three-digit code)?
Yes

BECAUSE
The effects of behavioural therapy and fluoxetine (Fluoxetin-Mepha®) were investigated in this randomized-controlled trial, which included adolescents between 12-16 years old, who suffered from major depressive disorder. This use corresponded with the approved indication (depression F32: Depressive episode).

Is the disease for which the IMP is administered in the clinical trial a self-limiting disease or condition?
No

BECAUSE
The effects of behavioural therapy and fluoxetine (Fluoxetin-Mepha®) were investigated in this randomized-controlled trial, which included adolescents between 12-16 years old, who suffered from major depressive disorder. A self-limiting disease is one that resolves spontaneously, with or without specific treatment. Major depression disorder is not considered a self-limiting disease. (The estimated remission rate of untreated major depression within 12 months is about 50%, though the rates may be higher in adolescents [Whiteford HA et al. Psychol Med 2013; 43: 1569-85]).

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Does the IMP's administration comply with standard medical practice as defined in a treatment guideline developed in accordance with international quality critieria?
No

BECAUSE
The effects of behavioural therapy and fluoxetine (Fluoxetin-Mepha®) were investigated in this randomized-controlled trial, which included adolescents between 12-16 years old, who suffered from major depressive disorder. There is no treatment guideline that recommends prescribing antidepressants to this population without also prescribing psychotherapy.

Does the intervention involve minimal risks and stress for the participating persons?
Yes

BECAUSE
The effects of behavioural therapy (18-20 sessions of individual therapy of 1 hour duration) and fluoxetine (Fluoxetin-Mepha®) were investigated in this randomized-controlled trial, which included adolescents between 12-16 years old, who suffered from major depressive disorder. Behavioural therapy is a type of psychotherapy that is not considered to be associated with more than minimal risk or stress.

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