BEISPIELSTUDIE

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

KATEGORISIERUNG

Gattung
Forschungsprojekt mit lebenden Personen

Art

Unterart
Klinischer Versuch mit Arzneimitteln (einschliesslich Kombinationen nach Art. 2 Abs. 1 Bst. f und g MepV)

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).

CATEGORISER-FRAGEN

Fällt das Forschungsprojekt in den Geltungsbereich des Humanforschungsgesetzes?
Ja

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®).

Handelt es sich bei dem Forschungsprojekt um ein Projekt mit lebenden Personen?
Ja

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

Handelt es sich bei dem Forschungsprojekt um einen klinischen Versuch im Sinne der KlinV oder der KlinV-Mep?
Ja

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").

Wird in der Studie ein Arzneimittel (einschliesslich Kombinationen nach Art. 2 Abs. 1 Bst. f und g Medizinprodukteverordnung (MepV) vom 1. Juli 2020) untersucht?
Ja

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

Wird in der Studie ein Medizinprodukt (In-vitro-Diagnostika ausgenommen) oder ein anderes Produkt nach Artikel 1 der Medizinprodukteverordnung (MepV) (Stand am 26. Mai 2022) untersucht?
Nein

BECAUSE

Wird in der Studie eine Intervention untersucht, die weder ein Heilmittel oder ein Transplantatprodukt, noch ein Produkt nach Art. 2a Abs. 2 Heilmittelgesetz (HMG) (Stand ab 26. Mai 2021) oder eine Transplantation ist?
Ja

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.

Wird in der Studie eine Gentherapie oder ein pathogener Organismus untersucht?
Nein

BECAUSE

Ist das Arzneimittel in der Schweiz zugelassen?
Ja

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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Wird in der Studie ein Placebo verwendet oder wird der Originalzustand des verwendeten Arzneimittels oder seine Verpackung verändert?
Nein

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.

Wird das Arzneimittel in der Studie gemäss Fachinformation angewendet?
Nein

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.

Wird von der Fachinformation nur in Bezug auf die Indikation oder die Dosierung abgewichen?
Ja

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).

Liegt die Indikation innerhalb derselben Krankheitsgruppe der ICD-10 Klassifizierung, wie sie in der Fachinformation aufgeführt ist (massgebend ist die mit dreistelligem Code definierte Krankheitsgruppe)?
Ja

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).

Handelt es sich bei der Krankheit für die das Arzneimittel im klinischen Versuch angewendet wird um eine selbstlimitierende Krankheit?
Nein

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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Entspricht die Anwendung einem medizinischen Standard, welcher als solches in einer nach international anerkannten Qualitätskriterien verfassten Leitlinie aufgeführt ist?
Nein

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.

Ist die Intervention mit höchstens minimalen Risiken und Belastungen für die Teilnehmenden verbunden?
Ja

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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