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A randomized, prospective, multicenter study of the effective treatments of panic disorder: cognitive behavioral therapy versus antidepressants versus combination therapy

Submission date
19/07/2006

Recruitment status
No longer recruiting

Registration date
19/07/2006

Overall study status
Completed

Last Edited
15/01/2015

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

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

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomized, prospective, multicenter study of the effective treatments of panic disorder: cognitive behavioral therapy versus antidepressants versus combination therapy

Acronym
PD-study

Study objectives
In the short-term, the combined treatment is expected to be superior to either mono-treatment. In the long-term, it is expected that cognitive behavioral therapy (CBT) will prove to be more durable and that patients taking selective serotonin reuptake inhibitor (SSRI) will require more mental health care during the one-year follow-up period.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
A randomized, prospective, multicenter study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Panic disorder

Interventions
CBT: the CBT protocol is based on the work of Clark and Barlow. Patients in the CBT group received up to 21 CBT sessions each lasting approximately 50 minutes. From session 16 onwards, sessions were scheduled with five-week intermissions. CBT consisted of the following:

1. Interoceptive exposure
2. Cognitive therapy
3. Exposure-in-vivo

SSRI group: patients receiving an SSRI visited their therapist 12 times, with weekly sessions during the first month and the remaining sessions distributed evenly over the treatment period of one year. Each visit lasted approximately 20 minutes. SSRIs used: fluvoxamine, sertraline, citalopram, fluoxetine, and cipramil. Tapering started three months before post-test.

Combination therapy of CBT and SSRI group: patients received both treatments, delivered in a parallel manner by different therapists.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Fluvoxamine, sertraline, citalopram, fluoxetine, cipramil

Primary outcome measure
Short-term:
1. Hamilton anxiety
2. Hamilton depression
3. Frequency of panic attacks
4. Responder status
5. Symptom checklist-90 (SCL-90)
6. Fear questionnaire-subscale
7. Agoraphobia

Long-term:
1. Remitter status
2. Panic coping
3. Quality of life
4. Hamilton anxiety
5. Hamilton depression

Secondary outcome measures
1. Treatment satisfaction
2. Locus of control
3. Fear of bodily sensations
4. Anticipation anxiety
5. Negative and positive self statements

Overall study start date
01/01/2001

Completion date
01/01/2006

Eligibility

Key inclusion criteria
Patients suffering from a primary diagnosis of panic disorder (PD) with or without agoraphobia (AG) (according to Diagnostic and Statistical Manual of mental disorders [DSM-IV] classification) recruited in 11 treatment facilities throughout the Netherlands between 1 April 2001 and 1 October 2003.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
150

Key exclusion criteria
1. Comorbid psychotic disorder
2. Drug dependence
3. Major affective disorder
4. Significant risk of suicidality
5. Pregnancy or lactation
6. Contraindications to either treatment modality

Date of first enrolment
01/01/2001

Date of final enrolment
01/01/2006

Locations

Countries of recruitment
Netherlands

Study participating centre
University Medical Center Groningen
Groningen
Netherlands
9700 RB

Sponsor information

Organisation
University Medical Center Groningen (UMCG) (The Netherlands)

Sponsor details
P.O. Box 30001
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Sponsor type
University/education

ROR
https://ror.org/03cv38k47

Funder(s)

Funder type
Research organisation

Funder Name
Netherlands Organisation for Health Research and Development (ZonMw)

Alternative Name(s)
Netherlands Organisation for Health Research and Development

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Netherlands

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	05/09/2013		Yes	No
Results article	results	01/04/2014		Yes	No