DELPHI-trial and DELPHI-SPECT.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22147

Source
Nationaal Trial Register

Brief title
DELPHI

Health condition

Major Depressive Disorder

Sponsors and support

Primary sponsor: n/a
Source(s) of monetary or material Support: ZonMw
PO-Box 93245
2509 AE the Hague
the Netherlands

Project numbers: 100-002-001 and 100-002-002

Intervention

Outcome measures

Primary outcome

1. Response and remission rates (decrease of >= 50% in HDRS-17 and HDRS-17 <= 7 respectively);

2. Total and specific (due to side-effects or inefficacy) drop-out.

Secondary outcome

1. Occurence of side-effects (physical and sexual);

2. Subjective well-being and MOS-SF36 quality of life;

3. Direct and indirect costs (TiC-P).

Study description

Background summary

Background:
Major depression is a major illness, with a year-prevalence of 5.8% in The Netherlands, and accounting for high costs regarding treatment and disability. Pharmacotherapy with Selective Serotonin Reuptake Inhibitors (SSRI) has become the first-choice treatment, but 50% of the patients treated show insufficient response to a first treatment of 6 weeks standard dose of a SSRI.
An often-used next-step strategy is dose-escalation: standard-dosages are doubled or tripled. After a systematic review, very little evidence for the efficacy of dose-escalation was found, previous studies investigated dose-escalation 3 weeks after initiation of treatment, which appears to be too early. Side effects undoubtedly increase with higher dosages. Patients are often reluctant to this strategy, but there is no systematic study of their perspectives. Additionally genetic polymorphisms of the serotonergic system are under examination as a possible explanation of the response rate to SSRIs. Prognostic factors to predict the efficacy of dose-escalation after several weeks of a standard-dose (meaning a form of patient-selection) would increase efficiency of this strategy.

AIM: 1.
To add evidence concerning efficacy, effectiveness and prognostic factors for the strategy of dose-escalation after 6 weeks on a standard dose of paroxetine.
AIM: 2.
To quantify patient perspectives regarding dose-escalation.

Design:

Randomized placebo-controlled trial of dose-maximization in depressed non- and partial responders after 6 weeks of a standard dose of a SSRI; Explorative study of prognostic factors (including genetic polymorphisms) for final response after dose-maximization.

Outcomes:

1. & 2. Response (> 50% decrease in 17-item Hamilton Depression Rating Scale (HDRS)), Remission (HDRS <8), Overall and specific drop-out, Subjective Well-being.

Comparisons:

Rates of dichotic outcomes and decreases in HDRS-scores during 6 weeks of follow-up in patients receiving increased dosages versus placebo-increase. Associations (in regression-models) of prognostic factors (demographic, genotypes of monoaminergic enzymes, Serotonin-Transporter and -receptors) with final response and interaction with dosage.

Study objective

Dose-escalation of paroxetine (up to 50 mg/day) does not increase efficacy of treatment of Major Depressive Disorder in patients who did not respond to a 6 week trial of paroxetine in a standard dose (20 mg/day).

Study design

N/A

Intervention

After 6 weeks of open treatment with a standard dose of paroxetine (20 mg/day) the patients who have not responded (<50% decrease in baseline HDRS-17) will be randomised to receive either a true or a placebo increase (by capsules) in addition to the standard dose.

Contacts

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Eligibility criteria

Inclusion criteria

1. Major Depressive Disorder according to DSM-IV (determined by Structured Interview for DSM-IV (SCID-I));

2. 17-item Hamilton Depression Rating Scale (HDRS-17) >18;

3. Age 18 to 70 years;

4. Maximally 1 previous treatment-trial with an antidepressant (of adequate duration [6 weeks] and dosage [maximum recommended dose]) for the current MDD episode.

Exclusion criteria

1. Bipolar disorder, psychosis or cognitive impairment (dementia or low IQ);

2. Use of psychoactive medication (except low doses of benzodiazepines);

3. Previous adequate trial with paroxetine with insufficient response for the current episode;

4. Primary alcohol- or drugs abuse;

5. MDD secundary to comorbid anxiety- or somatophorm disorder;

6. Somatic illnesses (e.g. untreated thyroid or other endocrine illnesses, systemic illnesses);

7. Pregnancy or wish to become pregnant;

8. Severe and acute suicidality;

9. Insufficient knowledge of Dutrch to fill in questionnaires.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2003
Enrollment:	500
Type:	Actual

Ethics review

Positive opinion

Date:	08-09-2005
Application type:	First submission

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
NTR-new	NL158
NTR-old	NTR193
Other	: N/A
ISRCTN	ISRCTN44111488

Study results

Summary results
N/A