

Effectiveness of infliximab (TNF-alpha antagonist) in the treatment of late-onset depressive spectrum disorder in patients of 60 years and above.

Gepubliceerd: 06-11-2006 Laatste bijgewerkt: 13-12-2022

Aetiology of late-onset depressive spectrum disorders may be different from the aetiology of early-onset depression. Concordant with the supposed aetiology of dementia, it has been postulated that chronic low grade immune activation plays a role in...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21203

Bron

Nationaal Trial Register

Verkorte titel

N/A

Ondersteuning

Primaire sponsor: Department of Psychiatry, Leiden University Medical Centre.

Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Severity of depression according to the Montgomery-Asberg Depression Rating Scale, 8 weeks after infliximab infusion.

Toelichting onderzoek

Achtergrond van het onderzoek

Background: Aetiology of late-onset depressive spectrum disorders may be different from the aetiology of early-onset depression. Concordant with the supposed aetiology of dementia, it has been postulated that chronic low grade immune activation plays a role in the aetiology of late-onset depressive spectrum disorders. Also, administration of a TNF-alfa antagonist in psoriasis was associated with increased wellbeing and decreased depressive symptoms, independent of improvement of the psoriasis. Therefore, we think that administration of the TNF-alpha antagonist infliximab may be effective in the treatment of late-onset depressive spectrum disorders.

Aim of this study: to determine the effectiveness of infliximab compared to placebo in the treatment of late-onset (first depressive episode above the age of 55 years), antidepressant resistant (one antidepressant) depressive spectrum disorders in patients of 60 years and above. Moreover, we want to investigate the effects of 1. LPS induced production capacity of cytokines in whole blood at baseline and 2. saliva cortisol concentrations at baseline, on outcome. Further, we will look into the influence of infliximab on presence and severity of apathy, and CRP plasma concentrations.

Design of the study: randomized placebo controlled double-blind study.

Methods: The Structured Clinical Interview for DSM-IV-TR (SCID) is used to confirm late-onset depressive spectrum disorder. Patients with bipolar disorder, psychotic features, severe suicidal thoughts or actions, severe cognitive impairment (MMSE<22/30), infection, tuberculosis and cardiac failure will be excluded. Patients are randomized into two groups, one receiving infliximab 3mg/kg intravenously (n=25), the other receiving placebo intravenously (n=25). Primary outcome is the effect on depressive symptoms 8 weeks after infusion, as assessed with the Montgomery-Asberg Depression Rating Scale (MADRS). Apathy is measured using Starkstein's Apathy Scale. Follow-up is done during 24 weeks.

Doel van het onderzoek

Aetiology of late-onset depressive spectrum disorders may be different from the aetiology of early-onset depression. Concordant with the supposed aetiology of dementia, it has been postulated that chronic low grade immune activation plays a role in the aetiology of late-onset depressive spectrum disorders.

Also, administration of a TNF-alfa antagonist in psoriasis was associated with increased wellbeing and decreased depressive symptoms, independent of improvement of the psoriasis.

Therefore, we think that administration of the TNF-alpha antagonist infliximab may be effective in the treatment of late-onset depressive spectrum disorders.

The aim of this study is to determine the effectiveness of infliximab compared to placebo in the treatment of late-onset, antidepressant resistant (one antidepressant) depressive spectrum disorders in patients of 60 years and above.

Onderzoeksproduct en/of interventie

One intravenous administration of infliximab 3mg/kg or placebo

Contactpersonen

Publiek

Leiden University Medical Center (LUMC), Department of Psychiatry, B1-P,
P.O. Box 750
D.W. Maas
Leiden 2300 RC
The Netherlands
+31 (0)71 5263785

Wetenschappelijk

Leiden University Medical Center (LUMC), Department of Psychiatry, B1-P,
P.O. Box 750
D.W. Maas
Leiden 2300 RC
The Netherlands
+31 (0)71 5263785

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients with depressive spectrum disorders (dysthymia, minor and major depression) using Standardised Clinical Interview for DSM-IV disorders;
2. Age > 60 years;
3. Late onset of depressive spectrum disorder (age > 55 years);
4. Resistant to at least 1 regular antidepressant drug, used for at least 6 weeks and in sufficient doses; or suffering from too many side effects of the antidepressant.

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

1. Psychotic features;
2. Bipolar disorder;
3. Severe suicidal thoughts or actions;
4. Serious infectious diseases;
5. (Suspicion of) tuberculosis;
6. Serious cardiac failure;
7. Prior treatment with recombinant antibodies;
8. Allergy to infliximab;
9. MMSE

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Dubbelblind
Controle:	Placebo

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	21-11-2006
Aantal proefpersonen:	50
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies	
Datum:	06-11-2006
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL790
NTR-old	NTR802
Ander register	: PO4.061
ISRCTN	ISRCTN65900535

Resultaten

Samenvatting resultaten

- Beekman AT, Geerlings SW, Deeg DJ, et al. The natural history of late life depression: a 6-year prospective study in the community. Arch Gen Psychiatry 2002; 59; 605-11.
- Biggelaar AHJ van den, Gussekloo J, Stek ML, Craen AMJ de, Frohlich M, Mast RC van der, Westendorp RGJ. Inflammation and the interleukin-1-signaling pathway contribute to depressive symptoms, but not cognitive decline in old age. Submitted for publication.
- Heun R, Kockler M, Papassotiropoulos A. Distinction of early- and late-onset depression in the elderly by their lifetime symptomatology. Int J Geriatr Psychiatry. 2000;15:1138-1142.
- Lyness JM, Moonseong H, Datto CJ, et al. Outcomes of minor and subsyndromal depression among elderly patients in primary care settings. Ann Int Med 2006; 144:496-504.
- Penninx BW, Kritchewsky SB, Yaffe K, Newman AB, Simonsick EM, Rubin S, et al. Inflammatory markers and depressed mood in older persons: results from the Health, Aging and Body Composition study. Biol Psychiatry 2003; 54:566-572.
- Rowe SK & Hyman Rapaport H. Classification and treatment of sub-threshold depression. Curr Opin Psychiatry 2006; 19:199-213.
- Stek M.L. et al. Prevalence, correlates and recognition of depression in the oldest old: the Leiden 85-plus study. J Affect Disord. 2004;78:193-200.
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- Tiemeier H, Hofman A, van Tuijl HR, Kiliaan AJ, Meijer J, Breteler MM (2003): Inflammatory proteins and depression in the elderly. *Epidemiology* 2003;14:103-107.