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

Submission date
28/12/2006

Recruitment status
No longer recruiting

Registration date
28/12/2006

Overall study status
Completed

Last Edited
05/08/2021

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
PO4.061, NL790, NTR802

Study information

Scientific Title
Effectiveness of infliximab (tumor necrotising factor-alpha antagonist) in the treatment of late-onset depressive spectrum disorder in patients of 60 years and above

Study objectives
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 Tumor Necrotising Factor (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.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the Medical Ethics Committee on the 22nd August 2006 (ref: P04.61).

Study design
Randomised, placebo controlled, parallel group, double blinded, multicentre trial

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

Depressive disorders

Interventions
One intravenous administration of infliximab 3 mg/kg or placebo.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Severity of depression according to the Montgomery-Asberg Depression Rating Scale, eight weeks after infliximab infusion.

Secondary outcome measures
1. Presence and severity of apathy, eight weeks after infliximab infusion
2. Change in plasmaconcentration of C-Reactive Protein (CRP), from baseline till eight weeks after infliximab infusion
3. Association of LipoPolySaccharide (LPS) induced production capacity at baseline and outcome of depression, eight weeks after infliximab infusion
4. Association of circadian cortisol rhythm at baseline and outcome of depression, eight weeks after infliximab infusion

Overall study start date
21/11/2006

Completion date
30/11/2007

Eligibility

Key inclusion criteria
1. Patients with depressive spectrum disorders (dysthymia, minor and major depression) using Standardised Clinical Interview for Diagnostic and Statistical Manual of Mental Disorders Fourth edition (DSM-IV) disorders
2. Age more than 60 years
3. Late onset of depressive spectrum disorder (age more than 55 years)
4. Resistant to at least one regular antidepressant drug, used for at least six weeks and in sufficient doses; or suffering from too many side effects of the antidepressant

Participant type(s)
Patient

Age group
Senior

Sex
Not Specified

Target number of participants
50

Key exclusion criteria
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. Mini Mental State Examination (MMSE) less than or equal to 22/30
10. Insufficient knowledge of the Dutch language

Date of first enrolment
21/11/2006

Date of final enrolment
30/11/2007

Locations

Countries of recruitment
Netherlands

Study participating centre
Leiden University Medical Center (LUMC)
Leiden
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Sponsor information

Organisation
Leiden University Medical Center (LUMC) (The Netherlands)

Sponsor details
Department of Psychiatry
P.O. Box 750
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Sponsor type

Hospital/treatment centre

Website
http://www.lumc.nl/english/start_english.html#http://www.lumc.nl/english/start_english.html

ROR
https://ror.org/05xvt9f17

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Leiden University Medical Center (LUMC) (The 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		01/06/2010	05/08/2021	Yes	No