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	Recruitment status No longer recruiting	Prospectively registered		
28/12/2006		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
28/12/2006	Completed	[X] Results		
Last Edited 05/08/2021	Condition category Mental and Behavioural Disorders	[] 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 lateonset 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 Netherlands 2300 RC

Sponsor information

Organisation

Leiden University Medical Center (LUMC) (The Netherlands)

Sponsor details

Department of Psychiatry P.O. Box 750 Leiden Netherlands 2300 RC

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