ISRCTN71047363 https://doi.org/10.1186/ISRCTN71047363

Exploring possible connections between vitamins D & B, inflammation and psychiatric disorders in elderly psychiatric in-patients

Submission date
20/11/2017

Recruitment status
No longer recruiting

Registration date
12/12/2017

Overall study status
Completed

Last Edited
01/10/2018

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Research has demonstrated that inflammation (swelling) is an integral part of several psychiatric disorders. Cytokines are molecules that regulate inflammation and can be used as inflammatory markers in peripheral blood (components of blood). Vitamin D and B have also been shown to be associated with both psychiatric disorders and inflammation, but the potential connection between these vitamins, inflammation and psychiatric disorders is still to be explored. Most studies have been conducted on younger adults and there are only a few studies on inflammation, vitamins and psychiatric disorders in elderlyThe aim of this study is to investigate possible association between vitamin D/B and inflammatory markers (cytokines) in elderly psychiatric patients.

Who can participate?
Patients aged 60 and older who are admitted to a psychiatric ward in Tromsø, Norway.

What does the study involve?
At admission and discharge, blood samples are collected from all patients. In addition to a standard analysis of the blood (checking number of red and white blood cells, liver and kidney function tests, electrolytes etc.), the blood is screened for molecules that signal inflammation. Presence of these molecules, called cytokines, indicates that there is an ongoing inflammation in the body and/or the brain, a phenomenon that have been demonstrated in various psychiatric disorders. Levels of vitamin D, various forms of vitamin B and sink, are also measured in the blood. The samples are assessed to see if there is any connection between lower levels of the vitamins and sink, and cytokines, as well as all these factors and psychiatric diagnosis and life style factors (smoking, alcohol, eating habits etc).

What are the possible benefits and risks of participating?
The patients in this study will receive assessment and treatment as usual, i.e. they will undergo standard procedures/treatment during their admission. Hence, being a part of the study does not entail an increased risk of complications, nor any directs benefits, compared to treatment as usual.

Where is the study run from?
University Hospital of Northern Norway (Norway)

When is the study starting and how long is it expected to run for?
March 2008 to July 2019

Who is funding the study?
Helse Nord RHF (Norway)

Who is the main contact?
Dr Erlend Bugge

Contact information

Type(s)
Scientific

Contact name
Dr Erlend Bugge

ORCID ID
http://orcid.org/0000-0003-2388-4251

Contact details
University Hospital of North Norway
Tromsø
Norway
9038

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PFP1298-16

Study information

Scientific Title
Vitamin D, vitamin B (B1,B6,B9,B12) og cytokiner hos pasienter innlagt ved Alderspsykiatrisk avdeling, UNN Tromsø/Vitamin D, vitamin B (B1,B6,B9,B12) and cytokines in gerontopsychiatric patients admitted to a psychiatric hospital

Study objectives

The aim of this study is to investigate possible association between vitamin D/B and inflammatory markers (cytokines) in gerontopsychiatric in-patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Committee for Medical and Health Research Ethics of Northern Norway, 05/02/2010 (amendment approved 02/02/2017), ref: REC North, reg. nr. 2009/1388)

Study design
Observational study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format. Please use the contact details to request the patient information sheet.

Health condition(s) or problem(s) studied
Various psychiatric conditions

Interventions
This is an observational study. Participating patients are assessed, diagnosed and treated according to standard procedure (“treatment as usual”). This includes psychometrics such as the MINI International Neuropsychiatric Interview, the Montgomery and Aasberg Depression Rating Scale, the Cornell Scale for Depression in Dementia, the Mini-Mental State Examination and the Clockdrawing Test. These psychometric tools, in combination with clinical interviews and reviews of medical records, are used by experienced clinicians in psychiatric assessment and diagnosis (according to ICD-10 research criteria). Furthermore, clinical somatic assessment, as well as array of blood samples (including cytokines), are undertaken for all patients. Other diagnostic /investigative procedures are carried out when deemed necessary (X-ray, CT, MRI, EEG, ECG etc.). Based on diagnosis/assessment, patients are treated with psychotherapy, family based therapy, psychoeducation and biological treatment (notably psychopharmacological treatment), or a combination thereof, or other treatments warranted. The median length of stay is 34 days (length of stay = observational period = duration of follow up). At discharge, self reported clinical status was categorized in 5 categories: Complete recovery, Almost complete recovery, Partial recovery, No recovery and Worsening.

Intervention Type

Other

Primary outcome measure
Levels of 27 cytokines in peripheral blood are measured using multiplex technology with a predefined kit (Bio-Plex Human Cytokine 27-Plex Panel) at admittance (IN) and discharge (OUT).

Secondary outcome measures
Levels of vitamin D, B1, B6, B9, B12 and sink in peripheral blood are measured using liquid chromatography–mass spectrometry and immunoassay methodology within the first week of admission.

Overall study start date
01/03/2008

Completion date
01/07/2019

Eligibility

Key inclusion criteria
1. Patients consecutively admitted to a gerontopsychiatric ward (wide inclusion)
2, Aged 60 and older

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Inability to communicate and cooperate, e.g. due to a severe psychiatric condition like severe dementia or confusion/delirium
2. Medical condition likely to significantly affect the blood/plasma analysis like severe dehydration or ongoing infection.

Date of first enrolment
18/03/2010

Date of final enrolment
09/12/2011

Locations

Countries of recruitment

Norway

Study participating centre
University Hospital of Northern Norway
Tromsø
Norway
9037

Sponsor information

Organisation
UIT The Arctic University of Norway

Sponsor details
Hansine Hansens veg 18
Tromsø
Norway
9019

Sponsor type
University/education

ROR
https://ror.org/00wge5k78

Funder(s)

Funder type
Government

Funder Name
Helse Nord RHF

Alternative Name(s)
Northern Norway Regional Health Authority

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Norway

Results and Publications

Publication and dissemination plan
Results from the study will be published in high-impact peer reviewed journals in 2018 and 2019.

Intention to publish date
01/06/2019

Individual participant data (IPD) sharing plan
Study protocol and participant level data will be available upon request. Please contact:

Erlend Bugge, MD
erlend.bugge@unn.no
University Hospital of North Norway
9038 Tromsø
Norway

Ole Grønli, MD, PhD
ole.k.grønli@unn.no
University Hospital of North Norway
9038 Tromsø
Norway

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	27/09/2018		Yes	No