

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	<input type="checkbox"/> Prospectively registered
Registration date 12/12/2017	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 01/10/2018	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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 elderly. The 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
<https://orcid.org/0000-0003-2388-4251>

Contact details
University Hospital of North Norway
Tromsø
Norway
9038

Additional identifiers

Protocol serial number
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

Study type(s)

Other

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(s)

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).

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Senior

Sex

All

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

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

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