

Vitamin D and non-specific musculoskeletal complaints in non-Western immigrants

Submission date 26/06/2013	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 12/07/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 25/06/2020	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Muscle pains without a known cause can last for months or years and are frequently seen in general practice. Also, vitamin D deficiency is a rather common condition, as is bad mood or depression. All these three conditions are more common in non-Western immigrants than they are in Caucasian people. Though a clear relation is known between bad mood or depression and muscle pain and though research found a relation between vitamin D deficiency and this complaint, it is still not sure that vitamin D supplementation can help to relieve these pains. Even more approximate is its effect on mood. This study aims to bring light on these issues and to help doctors and patients to make their decisions on vitamin D-supplementation.

Who can participate?

Non-Western immigrants, aged 16-60 years, with lasting muscle pain without any known cause and with low vitamin D levels in blood, can participate in this study.

What does the study involve?

Patients will be randomly allocated to either receive 2x150.000 IU vitamin D3 or placebo in 12 weeks, whilst they themselves nor their doctor knows which one. After these 12 weeks everybody gets a third dose, in the way that every patient has got at least one time vitamin D.

What are the possible benefits and risks of participating?

This treatment is surely harmless and the main drawback for participating is, that half of the patients get their vitamin D several weeks later. This study can help doctors to recognize depression in the participants. This is sometimes overlooked in general practice when language problems and cultural differences slow down good communication.

Where is the study run from?

The study is run from 25 general practices in Netherlands.

When is study starting and how long is it expected to run for?

The study is planned to start by March 2014 and is expected to last for two years.

Who is funding the study?

This study is funded by Merck (Netherlands) (Application in progress) and Het Achterstandsfonds fund (Netherlands).

Who is the main contact?

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Contact information

Type(s)

Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)

2013-002928-16

Protocol serial number

811700

Study information

Scientific Title

Vitamin D and non-specific musculoskeletal complaints in non-Western immigrants: a randomized controlled trial

Study objectives

Vitamin D supplementation can relieve non-specific musculoskeletal pain.

On 21/03/2014 the following changes were made to the trial record:

1. The anticipated start date was changed from 01/12/2013 to 20/03/2014
2. The anticipated end date was changed from 01/12/2015 to 20/03/2015
3. The target number of participants was changed from 230 to 240

Ethics approval required

Old ethics approval format

Ethics approval(s)

Applied: METCzwh, HAGA Hospital, The Netherlands

Study design

Randomized controlled trial (double blinded)

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Locomotor, Depression/bad mood, general practice

Interventions

Current interventions as of 21/03/2014:

Placebo and 200,000 IU Vitamin D (Verum) will be administered as a 10 ml bottle to drink under supervision at the office of the general practitioner, right after answering the questionnaires. Bottles nor fluid can be distinguished by aspect or taste.

Patients are randomized to two groups:

Treatment arm: Receives Verum on day 0 (baseline) and day 42

Placebo arm: Receives placebo on day 0 and day 42

Likert scales concern improvement, so will not be assessed at baseline.

Previous interventions:

Placebo and 150,000 IU Vitamin D (Verum) will be administered as a 7.5 ml bottle to drink under supervision at the office of the general practitioner, right after answering the questionnaires.

Bottles nor fluid can be distinguished by aspect or taste.

Patients are randomized to two groups:

Treatment arm: Receives Verum on day 0 (baseline), day 42 and placebo on day 84

Placebo arm: Receives placebo on day 0, day 42 and Verum on day 84

Likert scales concern improvement, so will not be assessed at baseline.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Cholecalciferol

Primary outcome(s)

Current primary outcome measures as of 21/03/2014:

Our primary goal is to assess the difference in self-reported improvement of pain (5-point Likert scale) 12 weeks after administration of placebo or 2 x 200.000 IU cholecalciferol. Measured on day 42, and day 84.

Previous primary outcome measures:

Our primary goal is to assess the difference in self-reported improvement of pain (5-point Likert scale) 12 weeks after administration of placebo or 2 x 150.000 IU cholecalciferol. Measured on day 42, day 84 and day 96.

Key secondary outcome(s)

Secondary outcome measures will be:

1. Self-reported improvement of pain in 6 weeks
 2. Improvement of mood at week six and week 12 and correlation of these improvements with level of 25-OH-D at start
 3. Correlation of improvement of mood with self-reported improvement of pain
 4. Improvement in ability to walk up the stairs at week six and week 12
 5. Correlation of VAS-scores for pain with self-reported pain (all 5 point Likert scales)
- Added 21/03/2014: 6. Correlation of self-reported improvement of pain in 12 weeks and 'bioavailable vitamin D' at baseline

All outcomes are measured on day 0, 42, 84 and 96.

Completion date

20/03/2015

Eligibility

Key inclusion criteria

1. Non-Western immigrants
 2. Aged 18-60 years
 3. 25-hydroxyvitamin D (25-OH-D) level less than 50 nmol/L
 4. Non-specific musculoskeletal complaints
 - 4.1. lasting for more than 12 weeks
 - 4.2. 3 periods in the last two years, each more than 1 month
- Note: depression is NOT an exclusion criterion

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

60 years

Sex

All

Key exclusion criteria

1. Vitamin D supplementation in the last 4 months
2. Rachitis
3. Low kidney function (creatinine > 150 nmol/L), Sarcoidosis, hypercalcaemia
4. ESR > 35, use of corticosteroids, cyclosporin, statins

Date of first enrolment

20/03/2014

Date of final enrolment

20/03/2015

Locations

Countries of recruitment

Netherlands

Study participating centre

Handellaan 108-D

Delft

Netherlands

2625 SN

Sponsor information

Organisation

Individual sponsor (Netherlands)

Funder(s)

Funder type

Industry

Funder Name

Het Achterstandsfonds fund (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration