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

Submission date
26/06/2013

Recruitment status
No longer recruiting

Registration date
12/07/2013

Overall study status
Completed

Last Edited
25/06/2020

Condition category
Musculoskeletal Diseases

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

EudraCT/CTIS number
2013-002928-16

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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.

Secondary outcome measures
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.

Overall study start date
20/03/2014

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 than12 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

Age group

Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
Both

Target number of participants
240

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
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Sponsor information

Organisation
Individual sponsor (Netherlands)

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Sponsor type
Other

Funder(s)

Funder type
Industry

Funder Name
Het Achterstandsfonds fund (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