ISRCTN54027991 https://doi.org/10.1186/ISRCTN54027991

Vitamin D supplementation and aspecific musculoskeletal disorders

Submission date
27/06/2007

Recruitment status
No longer recruiting

Registration date
27/06/2007

Overall study status
Completed

Last Edited
03/04/2013

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims.
Many non-Western immigrants suffer non-specific pain in arms, legs or backbone. These complaints are often diagnosed as fibromyalgia or depression and sometimes a lot of effort is put into finding specific causes. Many press and scientific reports suggest that these complaints may be caused by a lack of vitamin D, and recommend taking extra vitamin D (supplementation) as a cheap and harmless way to handle this hard-to-treat condition. This study tried to find out if this would be successful.

Who can participate?
Non-Western immigrants aged between 18 and 65 years who sought help for non-specific pains lasting longer than 3 months at their general practitioner and had low levels of vitamin D were asked to participate in this study.

What does the study involve?
Participants were randomly allocated to a dummy treatment (known as a placebo) or vitamin D (150,000 IU vitamin D3 orally); after 6 weeks, patients in the original vitamin D group were randomly allocated a second time to receive either vitamin D (again) or to switch to placebo, whereas patients in the original placebo group were all switched to vitamin D. At start and at 6 and 12 weeks after, they were interviewed by trained interpreters about their pain and ability to walk stairs. Neither participants nor interpreters were aware if the patient had received placebo or vitamin D.

What are the possible benefits and risks of participating?
Neither the participants nor their general practitioners had any financial benefit for participating. The used dose vitamin D3 was widely thought to be totally safe, so the main risk for (half of) the participants was being supplemented 6 weeks later than possible.

Where is the study run from?
8 practices in Delft, The Netherlands

When is the study starting and how long is it expected to run for?
The study started in 2007 and ended in 2011.

Who is funding the study?
This study was an investigator-driven study without any funding.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Study objectives
Vitamin D supplementation can relieve aspecific musculoskeletal disorders in allochtone patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from the local ethics committee (METC-zwh).

Study design
Randomised, double blinded, placebo controlled, crossover group, 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
Aspecific musculoskeletal disorders, vitamin D supplementation

Interventions
Due to difficulties obtaining study medication, the trial has been posponed. The trial was due to start on the 1st September 2007, and was posponed intially to 1st October 2007, but now is anticipated to start on the 1st September 2008.

Since the above mentioned changes to the start date, and as of 28th January 2008 the anticipated start date of this trial has now been finalised and is planning to start on the 4th February 2008.

150,000 IU vitamin D3 or placebo in one oral dose at week 0. Patients cross over to other treatment at week six (but: if given placebo at week 0, one will always get vitamin D3).

Intervention Type
Supplement

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Vitamin D

Primary outcome measure
Differences in improvement of pain as assessed by questionnaires at week 0 and 6 (between placebo and vitamin D3 groups).

Secondary outcome measures
1. Differences in improvement of pain as assessed by questionnaires at week 12 (between 150,000 and 300,000 vitamin D3-group)
2. Serum 25-OH-D levels at week 12 (150,000 and 300,000 group)
3. Differences in improvement of pain as assessed by questionnaires at week 6 and week 12 (between placebo - vitamin D3 group and vitamin D3 - placebo group)

4. Serum 25-OH-D levels at week 12 (placebo - vitamin D3 group and vitamin D3 - placebo group)
5. Correlations between localisation of complaints, improvement of pain as assessed by questionnaires, initial serum 25-OH-D levels and serum 25-OH-D levels at week 12
6. Differences in ability to walk stairs as assessed by questionnairies at week 6 and 12 between placebo and vitamin D group

Overall study start date
04/02/2008

Completion date
31/12/2011

Eligibility

Key inclusion criteria
1. Asian and African men and women, visiting their general practitioner
2. Aged 18 to 60 years
3. Greater than thirteen weeks aspecific musculoskeletal disorders (i.e., musculoskeletal complaints without a specific cause like:
3.1. Trauma or infection, or
3.2. Localisation (like gonarthrosis), or
3.3. Complex of symptoms (like Herniated Nucleus Pulposus [HNP], Polymyalgia rheumatica). Included are for instance low-back pain, fibromyalgia, fasciitis plantaris. Depression is NOT an exclusion criterion
4. Serum 25-hydroxyvitamin D (25-OH-D) level less than 50 nmol/ml

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
200

Key exclusion criteria
1. Pregnancy
2. Vitamin D supplementation in the last four months
3. Rachitis
4. Renal insufficiency
5. Sarcoidosis
6. Tuberculosis (TBC)
7. Peanut allergy
8. Use of cyclosporins, statins or oral steroids

Date of first enrolment
04/02/2008

Date of final enrolment
31/12/2011

Locations

Countries of recruitment
Netherlands

Study participating centre
Handellaan 108
Delft
Netherlands
2625 SN

Sponsor information

Organisation
Individual sponsor (Netherlands)

Sponsor details
c/o Dr F. Schreuder
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Sponsor type
Other

Funder(s)

Funder type
Other

Funder Name
Individual funder - Dr F. Schreuder (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	results	01/11/2012		Yes	No