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A randomised, double-blind, placebo-controlled trial of Vitamin D supplementation in the management of symptomatic knee osteoarthritis (the VIDEO study)

Submission date
05/04/2005

Registration date
03/05/2005

Last Edited
20/03/2017

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol
http://www.ctu.mrc.ac.uk/research_areas/study_details.aspx?s=43

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

15622

Study information

Scientific Title
A randomised, double-blind, placebo-controlled trial of Vitamin D supplementation in the management of symptomatic knee osteoarthritis (the VIDEO study)

Acronym
VIDEO (VItamin D Evaluation in Osteoarthritis)

Study objectives
Vitamin D supplementation may reduce the rate of disease progression and improve symptoms in participants with knee osteoarthritis.

On 29/03/2011 the anticipated end date was changed from 31/01/2009 to 31/08/2011.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised double-blind placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Knee osteoarthritis

Interventions
Participants will be randomised to receive oral vitamin D (as cholecalciferol) 800 IU/day (20 µg /day) or matching placebo tablets.

Intervention Type

Supplement

Phase
Not Applicable

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

Primary outcome measure
Radiological progression of knee OA in medial joint compartment at 36 months

Secondary outcome measures
1. Radiological progression of knee OA in other joint compartments
2. Reduction in pain and functional disability
3. Improvement in quality of life

Overall study start date
01/02/2004

Completion date
31/08/2011

Eligibility

Key inclusion criteria
1. Participants aged over 50
2. Male or female
3. Ambulatory (not wheelchair bound)
4. Able and willing to attend or comply with treatment and follow-up
5. Radiological evidence of early disease at medial tibio-femoral knee compartment (modified Kellgren & Lawrence [k&l] score 2/3, joint space width [JSW] >1 mm)
6. Pain in knee for most days of previous month
7. Written informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
800 (478 achieved as of 08/08)

Key exclusion criteria
1. Secondary osteoarthritis (OA), septic arthritis, gout, Wilson's disease, Paget's disease, pseudo gout
2. History of inflammatory arthritis

3. Knee stiffness >30 minutes duration
4. Current user of cod liver oil or vitamin D supplementation
5. Current use of glucosamine or chondroitin for less than 3 months
6. History of hyperparathyroidism or osteomalacia
7. Current use of anti-epileptic medication
8. Current use of bisphosphonates or use within 2 years
9. History of hypercalcaemia or hypercalciuria
10. History of hyperthyroidism, sarcoidosis
11. History of renal stones
12. Previous intra-articular injection: steroid within 3 months, hyalgan within 6 months
13. Previous knee surgery or arthroscopy within 6 months
14. History of osteoporotic fracture
15. History of cancer within last 5 years, excluding skin cancer
16. Serious psychiatric disorders including dementia
17. Inability to understand the procedures
18. Inability to attend or comply with treatment or follow-up scheduling
19. Pregnancy

Date of first enrolment
01/02/2004

Date of final enrolment
31/08/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Metabolic Unit
Stanmore
United Kingdom
HA7 4LP

Sponsor information

Organisation
Royal National Orthopaedic Hospital (UK)

Sponsor details
RNOH Stanmore
Brockley Hill
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Sponsor type
Not defined

ROR
https://ror.org/043j9bc42

Funder(s)

Funder type
Charity

Funder Name
Arthritis Research Campaign 15622

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	01/11/2016		Yes	No
Results article	sub study results	01/09/2017		Yes	No