

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	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 03/05/2005	Overall study status Completed	☐ Protocol
Last Edited 20/03/2017	Condition category Musculoskeletal Diseases	☐ Statistical analysis plan
		☒ 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

Contact name

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Contact details

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised double-blind placebo-controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Study participating centre

Metabolic Unit

Stanmore

United Kingdom

HA7 4LP

Sponsor information

Organisation

Royal National Orthopaedic Hospital (UK)

ROR

<https://ror.org/043j9bc42>

Funder(s)

Funder type

Charity

Funder Name

Arthritis Research Campaign 15622

Results and Publications

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