ISRCTN14533082 https://doi.org/10.1186/ISRCTN14533082

VASO - Vitamin D and arthroplasty surgery outcomes

Submission date
27/03/2017

Recruitment status
No longer recruiting

Registration date
03/04/2017

Overall study status
Completed

Last Edited
21/02/2022

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Vitamin D is essential for good health, because it helps our bodies to absorb calcium from the diet. There is a lot of evidence that having enough vitamin D can help prevent many diseases, such as heart disease, bone diseases and cancer. Although vitamins generally come from the diet, in the case of vitamin D, the majority of people actually get most of it from sunlight. Vitamin D deficiency or insufficiency is common in adults in the UK, particularly during the winter months where over 50% of adults are thought to have low Vitamin D levels. There is evidence that patients who are having knee or hip replacement surgery who have low vitamin D levels could have a poorer outcome and a longer stay in hospital. This study is looking at whether checking patient's Vitamin D levels before they have surgery can help to improve outcomes. 180,000 total hip or knee replacement procedures are performed each year in the UK and so if a link exists, the benefits of screening may be significant, as these deficient patients could start taking supplements to correct the deficiency before surgery until six months afterwards in order to improve outcomes.

Who can participate?
Adults who are scheduled to have hip or knee replacement surgery

What does the study involve?
Patients have their vitamin D levels measured at the beginning of the study. Those who are found to have low vitamin D levels are then randomly allocated into one of two groups. Those in the first group receive Vitamin D supplementation before surgery until six months after surgery, and those in the second group receive no vitamin D supplements. Participants in both groups are followed up using questionnaires six months after their surgery and have their medical records reviewed in order to assess how well they have recovered.

What are the possible benefits and risks of participating?
There are no direct benefits from taking part in the study, as currently it is not known whether screening and then treating Vitamin D deficiency before surgery is beneficial. However, it is hoped that the information from the study will help future patients having hip or knee replacement. There are no notable risks involved with participating.

Where is the study run from?
Five NHS hospitals in the north of England (UK)

When is the study starting and how long is it expected to run for?
January 2016 to November 2018

Who is funding the study?
Orthopaedic Research UK (UK)

Who is the main contact?
Dr Rory Morrison
rorymorrison@nhs.net

Study website
N/A

Contact information

Type(s)
Scientific

Contact name
Mr Rory Morrison

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
33969

Study information

Scientific Title
A prospective, randomised-controlled feasibility study investigating the benefit of screening for Vitamin D deficiency in a pre-operative elective arthroplasty setting

Acronym
VASO

Study objectives
A vitamin D level below normal (hypovitaminosis D or Vitamin D insufficiency/deficiency) is linked to a poorer outcome whereas a normal level is linked to an improved outcome following primary, elective hip or knee arthroplasty.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Yorkshire and The Humber - Bradford Leeds Research Ethics Committee, 13/03/2017, ref: 17/YH/0067

Study design
Randomised; Interventional; Design type: Treatment, Screening, Drug

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 to request a patient information sheet

Health condition(s) or problem(s) studied
Specialty: Musculoskeletal disorders, Primary sub-specialty: Other; UKCRC code/ Disease: Musculoskeletal/ Other osteopathies

Interventions
All patients in this feasibility trial will have their Vitamin D level checked before surgery, on the day of surgery and at 6 months after surgery. Those patients who, before their operation, are found to have a Vitamin D level below normal will be randomised to one of two groups.

Intervention group: Participants receive Vitamin D supplementation each day before surgery and for 6 months following surgery. The dosage of Vitamin D given is dependent on the patient's levels.
Deficiency (<25nmol/L): 20,000 units orally twice per week for 8 weeks then 1,600 units orally daily until 6 months following surgery
Insufficiency (25-49nmol/L): 1,600 units orally daily until 6 months following surgery.
Vitamin D levels are rechecked day of surgery and at 6-months following surgery

Control group: Participants receive no supplementation.

Participants are followed up six months post-surgery via questionnaires and medical record review.

Intervention Type
Supplement

Primary outcome measure
1. Pain and function is measured using the Oxford hip or knee score, collected by written questionnaire at baseline and 6 months
2. Health-related quality of life is measured using the EQ-5D collected by written questionnaire at baseline and 6 months

Secondary outcome measures
1. Length of hospital stay is collected from medical notes at endline
2. Medical complications including superficial and deep infection are collected from medical notes at endline
3. Readmission rates within 30 days of primary surgery are collected from medical notes at endline
4. Return to theatre rate within 30 days is collected from medical notes at endline
5. Mortality at 90-days is collected from medical notes at endline

Overall study start date
03/01/2016

Completion date
30/11/2018

Eligibility

Key inclusion criteria
1. Patients scheduled for primary total hip or knee arthroplasty
2. Aged over 18
3. Presenting at a participating trial site

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 100; UK Sample Size: 100

Total final enrolment
102

Key exclusion criteria
1. Lack of mental capacity to understand/comply with study procedures
2. Revision surgery
3. Known contraindication to Vitamin D treatment, e.g. previous diagnosis of sarcoidosis, primary hyperparathyroidism or other hypercalcaemic disorders, allergy
4. Renal impairment with eGFR <30 mL/minute
5. Already taking a Vitamin D supplement

Date of first enrolment
04/05/2017

Date of final enrolment
30/06/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Wansbeck General Hospital
Woodhorn Lane
Ashington
United Kingdom
NE63 9JJ

Study participating centre
North Tyneside General Hospital
Rake Lane
North Shields
United Kingdom
NE29 8NH

Study participating centre
Hexham General Hospital
Corbridge Road
Hexham
United Kingdom
NE46 1QJ

Study participating centre
James Cook University Hospital
Marton Road
Middlesbrough
United Kingdom
TS4 3BW

Study participating centre
The Friarage Hospital
Northallerton
United Kingdom
DL6 1JG

Sponsor information

Organisation
Northumbria Healthcare NHS Foundation Trust

Sponsor details
North Tyneside General Hospital
Rake Lane
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England
United Kingdom
NE29 8NH
+44 (0)191 293 4087
ResearchAndDevelopment@northumbria-healthcare.nhs.uk

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01gfeyd95

Funder(s)

Funder type
Charity

Funder Name

Orthopaedic Research UK

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed journal and presentation at relevant scientific meetings.

Intention to publish date
30/11/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to a lack of participant consent.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	02/11/2017		Yes	No
HRA research summary			28/06/2023	No	No